SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: SB 342

SPONSOR: Senator Clary and others

SUBJECT: Pharmacy

DATE: April 16, 2001 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Fav/1 amendment
2.	Emrich	Deffenbaugh	BI	Favorable
3.	Peters	Belcher	AHS	Favorable
4.	Peters	Wood	AP	Favorable
5.				
6.				

I. Summary:

This bill requires the Board of Medicine and the Board of Pharmacy to remove from the "negative" formulary for generic and brand-name drugs all drugs that have been determined therapeutically equivalent or "AB" rated in the *Orange Book* published by the federal Food and Drug Administration, effective July 1, 2001. Thus, the practical effect of this bill would allow pharmacists to dispense a generic form of the particular drug instead of the brand-name version. The bill specifies that it does not alter or amend existing law authorizing a physician to prohibit generic drug substitution by writing "medically necessary" on the prescription. The bill takes effect upon becoming law.

The bill creates two sections of law that have not been designated in the Florida Statutes.

II. Present Situation:

The federal Food and Drug Administration (FDA) evaluates and controls prescription drug products marketed in the United States. The FDA monitors the therapeutic equivalency of brand-name (innovator) and generic drugs marketed in the United States and makes specific findings regarding equivalence in its publication, "*Approved Drug Products with Therapeutic Equivalence Evaluations,*" referred to as the *Orange Book*. A generic drug product and the innovator drug are considered to be bioequivalent by the FDA when the rate and extent of absorption of the test drug do not show significant difference from the rate and extent of absorption of the reference innovator drug, and when the active ingredient is administered at the same dose under similar experimental conditions in a single dose or multiple doses.

The FDA has established statistical criteria for determining bioequivalence between a generic drug seeking approval and the reference (innovator) drug. The FDA *Orange Book* was initially

available in 1980 to provide therapeutic evaluations and public information and advice to state health agencies, prescribers, and pharmacists in the area of drug product selection. Drug products listed in the *Orange Book* are assigned therapeutic equivalence codes: "A" rating indicates drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products because they have no known or suspected bioequivalence problems, or actual bioequivalence problems have been resolved by in vivo or in vitro data confirming bioequivalence; and the "B" rating indicates drug products that FDA considers to not be therapeutically equivalent to other pharmaceutical drug products; or the "B*" rating indicates drug products that require further FDA investigation and review to determine equivalence.

The drug products are listed in the *Orange Book* according to active ingredient, dosage form, and strength. The *Orange Book* uses a series of two letter codes to identify the therapeutic equivalency evaluation findings of the FDA. The first letter of the code identifies whether a drug is considered to be therapeutically equivalent. The second letter identifies the basis for the equivalence evaluation and is often dependent on the dosage form, delivery system, or route of administration. A third character may be added to provide additional information on the basis of FDA's evaluations. For example, an "AB" evaluation generally denotes products that contain an active ingredient in a dosage form for which adequate studies establish the bioavailability and bioequivalence of its drug product. Three-character codes such as, "AB1, AB2…" are assigned only in situations when more than one reference listed drug of the same strength has been designated under the same heading. Two or more reference-listed drugs are generally selected only when there are at least two potential reference drug products that are not bioequivalent to each other.

The *Orange Book* states that drug products are classified by the FDA as therapeutically equivalent when they meet five criteria:

(1) Are approved as safe and effective;
(2) Are pharmaceutical equivalents in that the drug products contain **identical amounts of the same active ingredient in the same dosage form and route of administration**;
(3) Are **bioequivalent** in that the drug products do not present a known or potential problem, and they meet an acceptable in vitro standard, or, if the drug products do present such a known or potential problem, the drug products are shown to meet an appropriate bioequivalence standard;
(4) Are **adequately labeled**; and,
(5) Are manufactured in compliance with **Current Good Manufacturing Practice** regulations.

When these criteria are met, therapeutically equivalent drug products may be substituted for each other because safety and effectiveness have been demonstrated.

In addition to federal requirements for brand-name drugs and generic drugs, Florida and 21 other states impose additional restrictions on the substitution of generic drugs for name brand drugs dispensed to consumers. Pursuant to s. 465.025, F.S., a pharmacist who receives a prescription for a brand name drug must, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of the prescription, or in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the

brand name drug prescribed is medically necessary. The pharmacist has an affirmative duty to inform the person presenting a prescription of any substitution of a generic drug product for a brand name drug product, of any retail price difference between the drugs, and of the person's right to refuse the substitution.

Section 465.025(6), F.S., requires the Board of Pharmacy and the Board of Medicine to adopt by rule, a drug formulary that lists medicinal drugs which have been specifically determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. This formulary is known as the "negative" drug formulary. The Board of Pharmacy and the Board of Medicine have adopted a negative drug formulary, by rule. A pharmacist is prohibited from substituting a prescription for a brand name drug product with a generic drug if the brand name drug product or the generic drug product has been listed on the negative drug formulary.

The Florida Board of Medicine and the Board of Pharmacy adopted the original negative drug formulary in 1976. Since the initial negative drug formulary was adopted in 1976, it has only been amended by petition of interested parties, usually drug manufacturers. The review process for the negative drug formulary includes initial consideration by a hired consultant, who in turn makes a non-binding recommendation to a five-member committee. The negative drug formulary committee makes a non-binding recommendation to the Board of Medicine and the Board of Pharmacy regarding changes to the negative formulary. The person seeking an amendment to the negative drug formulary must submit information in support of the request that meets the burden of proof to show cause why the amendment should be made.

The negative drug formulary is currently codified at 64B16-27.500, Florida Administrative Code. There are 11 drugs currently included on the negative formulary which are listed along with the initial year they were added to the negative formulary: digoxin (1976); digitoxin (1976); warfarin (1976); conjugated estrogen (1976); quinidine gluconate (1976); dicumarol (1977); phenytoin (1976); chlorpromazine (1981) - limited to oral dosage forms (1982) - limited to solid oral dosage forms (1992); theophylline (controlled release) (1982); levothyroxine sodium (1984); and pancrelipase oral capsules (1990) - limited to oral dosage forms (1992).

During the 1999-2000 interim, the Committee on Health, Aging and Long-Term Care completed a review of the negative drug formulary and identified a number of weaknesses in the use of Florida=s negative drug formulary to restrict drug substitution. The committee staff report (Interim Project Report 2000-55) concludes that generic drugs may be safely substituted for brand-name products in the professional judgment of the dispensing pharmacist when such drugs have met FDA=s bioequivalence standards. The committee staff report provides detailed findings regarding the negative drug formulary for generic substitution. The committee staff report may be found at:

http://199.44.49.2/data/Publications/2000/Senate/reports/interim_reports/pdf/00-55hc.pdf

III. Effect of Proposed Changes:

The bill requires, effective July 1, 2001, the Board of Pharmacy and the Board of Medicine to remove from the "negative" drug formulary, all drugs that have been determined therapeutically equivalent or "AB" rated in the *Orange Book* published by the federal FDA. The following generic drugs currently listed on the negative formulary specified in s. 465.025(6), F.S., have been determined to be therapeutically equivalent or "AB" rated in the *Orange Book* published by the federal FDA according to the staff with the Florida Board of Pharmacy: digoxin; warfarin; quininidine gluconate; phenytoin; and theophylline (controlled release). Thus, adoption of the bill would lead to the removal of these 5 drugs from the negative formulary. Therefore, the practical effect of this bill would allow pharmacists to dispense a generic form of the particular drug instead of the brand-name version. The bill further specifies that it does not alter or amend existing law in s. 465.025, F.S., providing for the authority of physicians to prohibit generic drug substitution by writing "medically necessary" on the prescription. The bill takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Consumers and other third party payors may save costs if generic substitution was permitted in community pharmacies for drugs currently on the negative drug formulary that have been determined to be therapeutically equivalent or "AB" rated in the federal FDA's *Orange Book*.

C. Government Sector Impact:

According to the Florida Department of Health, state government purchasers could save $103,785 each year by purchasing generic equivalents of the brand-name drugs listed in the negative drug formulary specified in s. 465.025(6), F.S. The purchasers include all state institutions, agencies and political subdivisions which use the statewide pharmaceutical contract.

The Agency for Health Care Administration has indicated that the Florida Medicaid program could save an estimated $4 million, annually if the less expensive generic drugs are substituted for the brand-name products which are listed on the negative drug formulary. Any savings realized will be offset by the availability of any rebates offered by manufacturers of the brand-name products. The agency reports that increased competition in the generic market for products currently on the negative formulary would be expected to result in lower generic drug prices which could ultimately benefit the Medicaid program.

VI. Technical Deficiencies:

In reference to the bill: on page 1, line 18, the bill refers to "A-B" rated which may be interpreted as "A-to-B" rated or "A" rated to "B" rated. The correct reference should be "AB" rated.

VII. Related Issues:

None.

VIII. Amendments:

#1 by Health, Aging and Long-Term Care:
Removes from the negative drug formulary any generic drug for which all commercially marketed equivalents of that drug product are "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug in the *Orange Book.* According to the staff with the Board of Pharmacy, the effect of this amendment would require 4 drugs (digoxin, warfarin, quinidine gluconate, and phenytoin) to be taken off the negative drug formulary and allow 1 drug (theophylline-controlled release), which was taken off the formulary by the original bill, to remain on the negative formulary.

Comments by Appropriations on Amendment #1 – The Agency for Health Care Administration estimated that gross Medicaid costs will be reduced in excess of 400,000 per year through the use of the generic equivalent products warfarin, digoxin, phenyton, and quindine gluconate. The agency reports that the State of Florida will save in excess of $1 million per year by choosing the less expensive generic equivalent in place of the brand product.