SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: SB 370

SPONSOR: Health, Aging and Long-Term Care Committee and Senators Silver, Latvala, and Klein

SUBJECT: Pharmacy/Negative Drug Formulary

DATE: February 18, 2000 REVISED: 3/15/00

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Fav/1 amendment
2.				
3.				
4.				
5.				

I. Summary:

The bill requires the Board of Medicine and the Board of Pharmacy to make recommendations to the Legislature concerning the formulary for generic and brand-name drugs. The boards must jointly submit a report to the Legislature by January 1, 2001, which recommends whether the negative drug formulary required by section 465.025(6), Florida Statutes, should be retained. If the report recommends retention of the formulary, the report must specify how further restrictions on generic drug substitution will be based solely on scientific evidence of drug equivalency and what standards and evidence will be used in making such determinations and must estimate the costs of making drug equivalency determinations in Florida.

Effective July l, 2001, this bill repeals section 465.025(6), F.S.

II. Present Situation:

The federal Food and Drug Administration (FDA) evaluates and controls prescription and generic drug products marketed in the Unites 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, 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, 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 *Orange Book* states that drug products are classified by 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**; (5) and 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. The drugs currently included on the negative formulary 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.

III. Effect of Proposed Changes:

The bill requires the Board of Medicine and the Board of Pharmacy to jointly submit a report to the Legislature by January 1, 2001, which recommends whether the formulary for generic and brand-name drugs required by section 465.025(6), F.S., should be retained. If the report recommends retention of the formulary established under s. 465.025(6), F.S., the report must specify how further restrictions on generic drug substitution will be based solely on scientific evidence of drug equivalency and what standards and evidence will be used in making such determinations and must estimate the costs of making drug equivalency determinations in Florida.

Effective July l, 2001, this bill repeals section 465.025(6), F.S.

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 Article VII, Section 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 Article I, Subsections 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 Article III, Subsection 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 required under s. 465.025(6), F.S.

Under the State of Florida's epilepsy program, the central pharmacy within the Department of Health currently purchases the brand-name drug Dilantin®, instead of a less expensive generic form of the drug (phenytoin) because the drug is listed on the negative drug formulary. If the negative drug formulary is repealed, the Department of Health will purchase Dilantin® or the generic version of the drug (phenytoin), whichever is cheaper under state competitive bidding procedures. Patients whose physicians prescribe Dilantin® as "medically necessary" and who get their prescriptions filled from the central pharmacy as part of the Department of Health's epilepsy program may incur additional costs to obtain the brand-name drug from another pharmacy which maintains a consistent supply of the brand-name drug, if Dilantin® is otherwise unavailable through the central pharmacy.

C. Government Sector Impact:

The Florida Medicaid program estimates that it could save $1.9 million per quarter if generic substitution was permitted for those drugs listed on the negative drug formulary.

Under the State of Florida's epilepsy program, the central pharmacy within the Department of Health currently purchases the brand-name drug Dilantin®, instead of a less expensive generic form of the drug (phenytoin) because the drug is listed on the negative drug formulary. If the negative drug formulary is repealed, the Department of Health will most likely purchase the generic form of Dilantin® (phenytoin) which the department estimates will save approximately $109,122 each year. According to the Department of Health, the State of Florida purchasing rules require the central pharmacy to purchase the least expensive form of a drug due to procedures for competitive bid awards made by the state. The Department of Health noted that the central pharmacy will not have the option of purchasing the brand-name drug Dilantin®, if the generic drug is cheaper, even though many doctors may consider the brand-name drug as medically necessary in treating their patients.

VI. Technical Deficiencies:

None.

VII. Related Issues:

For further information about the negative drug formulary, please read Senate Interim Project Report 2000-55.

Since the interim project was originally presented to the committee, the Board of Pharmacy, the Board of Medicine, and the Negative Drug Formulary Committee have met and discussed the recommendations contained in the interim project report:

- The Board of Pharmacy discussed the interim project report at its October 4th meeting. In response to the report, the board's executive director stated that: "The Board of Pharmacy is aware of no scientific evidence to present at this time to justify the continued existence of the negative formulary. However the board will ask the Negative Formulary Committee to see if such evidence is available."

- The Board of Medicine discussed the possible repeal of the statutory provisions relating to the negative drug formulary at the board's October 8-9th meeting and a consensus of the board was in opposition to the proposed repeal. The Board of Medicine members believe that there is evidence despite the federal Food and Drug Administration's evaluation of therapeutic equivalency that the brand-name drug can be more beneficial and that the generic brand can be harmful or non-therapeutic in some cases.

- The Negative Drug Formulary Committee met on November 1, 1999, to discuss the interim project report and, after discussion, the committee unanimously agreed that the State of Florida should apply the federal Food and Drug Administration's therapeutic equivalency standard for generic drugs (the *Orange Book*) for multi-source drug products. The committee also recommended that the Negative Drug Formulary Committee be retained or some similar mechanism be established to review those multi-source drug products exempt from the 1984 Drug Price Competition and Patent Term Restoration Act (Waxman-Hatch Act).

VIII. Amendments:

#1 by Health, Aging and Long-Term Care:
Removes the July 1, 2001 repeal of the formulary established under section 465.025(6), F.S., and, effective July 1, 2000, requires the Board of Pharmacy and the Board of Medicine to remove from the formulary all drugs that have been determined therapeutically equivalent or AB-rated in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the Federal Food and Drug Administration. The effective date of the bill is revised to take effect upon becoming a law.