STORAGE NAME: h0069z.hr.doc
DATE: December 10, 2001

****AS PASSED BY THE LEGISLATURE****
CHAPTER #: 2001-146, Laws of Florida

HOUSE OF REPRESENTATIVES
AS FURTHER REVISED BY THE
HEALTH REGULATION COMMITTEE
FINAL ANALYSIS

BILL #: HB 69

RELATING TO: Drugs/Generic and Brand-Name

SPONSOR(S): Representative(s) Argenziano, Fasano, and others

TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH REGULATION YEAS 10 NAYS 0
(2) FISCAL POLICY & RESOURCES YEAS 12 NAYS 0
(3) COUNCIL FOR HEALTHY COMMUNITIES YEAS 15 NAYS 0
(4)
(5)

I. SUMMARY:

On May 2, 2001, 1st ENG/HB 69 passed the Senate and was ordered enrolled. It was signed by the Officers and presented to the Governor on May 18, 2001 and on June 1, 2001, was approved by the Governor and became Chapter 2001-146, Laws of Florida. The effective date of the act was June 1, 2001.

This bill removes from the negative formulary any generic drug for which every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug in the *Orange Book.* The bill specifies that physicians may still prohibit generic substitution of these drugs by writing "medically necessary" on the prescription in accordance with current law. According to staff of the Board of Pharmacy, the bill would remove four (4) drugs from the negative formulary: warfarin; digoxin; phenytoin; and quinidine gluconate.

In June 2001, the Board of Medicine and the Board of Pharmacy adopted a rule to remove from the Negative Drug Formulary the following drugs: warfarin; digoxin; phenytoin; and quinidine gluconate. The rule was challenged thereby delaying implementation.

The Board of Pharmacy filed an Emergency Rule to take effect on November 10th; however, the First District Court of Appeal entered an Order on November 8th which stayed the effect of the Emergency Rule. Just recently, the pharmaceutical company which challenged the original and emergency rules dropped its challenges thereby allowing the new rule to become effective on December 5, 2001.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes [X]	No []	N/A []
2.	Lower Taxes	Yes []	No []	N/A [X]
3.	Individual Freedom	Yes [X]	No []	N/A []
4.	Personal Responsibility	Yes [X]	No []	N/A []
5.	Family Empowerment	Yes []	No []	N/A [X]

For any principle that received a "no" above, please explain:

B. PRESENT SITUATION:

Section 465.025, F.S., provides for the automatic substitution of generic drugs for brand name drugs, an action that is intended to provide for a more economical generic equivalent for the patient. Subsection (6), provides a mechanism to restrict the substitution of certain drug products when the Board of Medicine and the Board of Pharmacy have determined that substitution of that particular drug "would pose a threat to the health and safety of patients." This mechanism is called a "negative drug formulary."

Established over twenty years ago, the negative formulary currently contains eleven drugs listed by generic name. The boards have employed outside consultants and have named a joint committee to provide recommendations when petitions for modifications have been received. The five-person joint committee includes two pharmacist members of the Board of Pharmacy and two physician members of the Board of Medicine. The Boards vote independently on the petition and must concur for a modification to occur. The eleven drugs are: digoxin, digitoxin, warfarin, conjugated estrogen, quinidine gluconate, dicumarol, phenytoin, chlorpromazine, theophylline, levothryroxine sodium, and pancrilipase.

The federal Food and Drug Administration (FDA) reviews generic drugs and determines which generics should be rated therapeutically equivalent. Those therapeutically equivalent generic drugs are then published in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations,* more commonly known as the "Orange Book." Pharmacists rely on the information contained in the FDA Orange Book when determining which generic drugs may be safely substituted for brand name drugs.

An example of how this automatic substitution process occurs in Florida:

> Doctors usually write prescriptions using the brand name drug since those brand names are made known to the doctor through marketing by pharmaceutical manufacturers and wholesalers and through reading medical literature. The patient then takes the prescription to the pharmacy of his or her choice and the pharmacist fills that prescription. The pharmacist will automatically dispense a generic form of the drug instead of the brand name version unless the patient asks for the brand name only and is willing to pay for the difference in cost, if any, OR if the doctor has written on the face of the prescription in his own handwriting the words "MEDICALLY NECESSARY." The third exception to the automatic substitution of a generic drug for the brand

name drug is when the drug is listed on the negative drug formulary. When a doctor writes an outpatient prescription for a brand name version of a drug listed on the negative drug formulary, substitution of the generic drug by the pharmacist is precluded. The pharmacist may only dispense the brand name drug as written by the doctor.

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.

The negative formulary restriction applies only in the community pharmacy setting, e.g. Eckerd, Walgreen. Institutional pharmacies, such as hospital inpatient settings and correctional facilities, are specifically exempted by statute and may substitute a generic drug for the brand-name even if the doctor's orders are written for the brand-name drug and the drug is listed on Florida's negative drug formulary.

Although the generic versions of the drugs are currently available to consumers when the prescription is written by the doctor specifically for the generic drug, removal of therapeutically equivalent generic drugs from the negative formulary could facilitate expanded use of the generic versions of these drugs.

One of the drugs listed on the negative drug formulary is Warfarin, also known as Warfarin Sodium. The brand name drug, Coumadin®, is manufactured by DuPont Pharmaceuticals Company. There are at least three generic drug manufacturers, including Barr Laboratories, which have developed a generic drug determined by the FDA to be therapeutically equivalent. Barr Laboratories previously filed a petition with the Florida Board of Pharmacy and the Florida Board of Medicine requesting that Warfarin be removed from the negative drug formulary. However, prior to final action by the Board of Medicine and the Board of Pharmacy, the petition was withdrawn. Since the boards have not removed Warfarin from the negative drug formulary in Florida, pharmacists are precluded from automatically substituting generic Warfarin whenever a prescription is written by a doctor for Coumadin®.

During the 1999-2000 interim, the Senate 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 "Review of the Negative Drug Formulary Established Under Section 465.025, Florida Statutes" (Interim Project Report 2000-55) concludes "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 report provides detailed findings regarding the negative drug formulary for generic substitution.

C. EFFECT OF PROPOSED CHANGES:

This bill requires the Board of Pharmacy and the Board of Medicine to remove from the Negative Drug Formulary any generic drug for which every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed in the *Orange Book.* The bill specifies that physicians may still prohibit generic substitution of these drugs by writing "medically necessary" on the prescription in accordance with current law. According to staff of the Board of Pharmacy, the bill would remove four (4) drugs from the negative formulary: digoxin; warfarin; phenytoin; and quinidine gluconate.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Requires the Board of Pharmacy and the Board of Medicine to remove from the Negative Drug Formulary any generic drug for which every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed in the *Orange Book.*

Section 2. Specifies that physicians may still prohibit generic substitution of these drugs by writing "medically necessary" on the prescription in accordance with current law.

Section 3. Provides an effective date of upon becoming law.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See Fiscal Comments section.

2. Expenditures:

See Fiscal Comments section.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See Fiscal Comments section.

D. FISCAL COMMENTS:

The Department of Health, Bureau of Pharmacy Services, reports that the fiscal impact to the state would be a savings of $103,785 annually. This includes all drug purchases by the state, including all state agencies, institutions, and political subdivisions.

The Agency for Health Care Administration, Division of Medicaid, estimates that using the less expensive generic equivalent, instead of the brand-name drug, would save the state approximately $4 million per year; however, the agency notes that the reduction in rebates from the brand-name manufacturer may offset those savings to the state.

The Agency for Health Care Administration anticipates that patients and commercial insurers could benefit from this bill since they do not participate in the federal rebate program. Additionally, the agency reports that increased competition in the generic market for these products would be expected to result in lower generic drug prices that could ultimately benefit Medicaid as well.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require a city or county to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that cities and counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with cities or counties.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

The bill does not provide any new specific rulemaking authority. However, it does require the Board of Pharmacy and Board of Medicine to amend an existing rule.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On February 6, 2001, the Committee on Health Regulation adopted one amendment, which is traveling with the bill. This amendment clarifies that only those drugs where every product marketed has been

determined to be therapeutically equivalent will be removed from the Negative Drug Formulary. This would remove only four drugs: warfarin, phenytoin, quinidine gluconate, and theophylline.

On March 22, 2001, the Council for Healthy Communities adopted a "strike everything" amendment, which is traveling with the bill. The amendment removes from the negative formulary any generic drug for which every commercially marketed equivalent of that drug product is "A" rated as therapeutically equivalent to a reference listed drug or is a reference listed drug in the *Orange Book.* According to staff with the Board of Pharmacy, the effect of this amendment would require four (4) drugs (digoxin, warfarin, quinidine gluconate, and phenytoin) to be taken off the negative drug formulary and allow one (1) drug (theophylline-controlled release), which was taken off the formulary by the original bill, to remain on the negative formulary.

On April 4, 2001, the "strike everything" amendment adopted in the Council for Healthy Communities was adopted on the House Floor. No other amendments were adopted.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:	Staff Director:
Lucretia Shaw Collins	Lucretia Shaw Collins

AS REVISED BY THE COMMITTEE ON FISCAL POLICY & RESOURCES:

Prepared by:	Staff Director:
Doug Pile	Greg Turbeville

AS FURTHER REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES:

Prepared by:	Council Director:
Lucretia Shaw Collins	Mary Pat Moore

FINAL ANALYSIS PREPARED BY THE COMMITTEE ON HEALTH REGULATION:

Prepared by:	Staff Director:
Lucretia Shaw Collins	Lucretia Shaw Collins