

**The Florida Senate**  
**PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT**

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

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Prepared By: Health Regulation Committee

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BILL: SB 1836

INTRODUCER: Senator Jones

SUBJECT: Antiepilepsy Drugs

DATE: March 18, 2007

REVISED: 03/22/07

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	Fav/1 amendment
2.			GA	
3.				
4.				
5.				
6.				

**Please see last section for Summary of Amendments**

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Technical amendments were recommended

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Amendments were recommended

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Significant amendments were recommended

**I. Summary:**

The bill amends the requirements for generic substitution for brand-name prescription drugs to prohibit a Florida-licensed pharmacist from “interchanging” or substituting an antiepileptic drug or formulation of an antiepileptic drug, brand or generic, for the treatment of seizures or epilepsy without prior notification of and the signed, informed consent to such interchange from the prescribing physician and the patient or the patient’s parent, legal guardian, or spouse. For purposes of the prohibition, interchanging includes substituting any antiepileptic drug or formulation for the antiepileptic drug prescribed.

The generic substitution law is also amended to create an exception for antiepileptic drugs to its requirements for a Florida-licensed pharmacist to substitute a generic drug for a brand name drug when the pharmacist receives a prescription for a brand name drug.

This bill amends ss. 440.13, 465.025, 465.0251, F.S.

## **II. Present Situation:**

### **Epilepsy**

Epilepsy is a chronic neurological condition characterized by recurrent seizures that are not caused by any other medical condition such as low blood sugar.<sup>1</sup> About fifty million people are living with epilepsy in the world and greater than 2.7 million in the United States.<sup>2</sup> With epilepsy, the electrical rhythms of the brain tend to become imbalanced and result in recurrent seizures. Epilepsy causes an electrical disturbance in the brain. Medication controls seizures for the majority of patients. The seizures for refractory epilepsy, a severe form of the disease, may not be controlled by medications alone. Epilepsy is treated with medications that have a host of side effects, which may cause problems with learning, memory, and behavior. The illness may consume the energy and financial resources of persons with epilepsy and their families.

The Florida Department of Health administers a program for the care and assistance of persons with epilepsy and promotes and assists in the continued development and expansion of programs for the case management, diagnosis, care, and treatment of such persons, including required pharmaceuticals, medical procedures, and techniques which will have a positive effect in the care and treatment of persons with epilepsy.<sup>3</sup>

### **Generic Drug Substitution**

Florida law requires a less expensive generically equivalent drug to be substituted for a brand name drug unless the patient objects or the prescribing practitioner affirmatively prohibits the substitution by writing on the prescription that the brand name drug is medically necessary.<sup>4</sup> A “generically equivalent drug product” is defined to mean a drug product with the same active ingredient, finished dosage form, and strength. The generic substitution law only applies to drugs that are prescribed by brand name. If the prescription is written for a drug identified by its generic name, the pharmacist may use her or his professional judgment to select any drug product with the same active ingredients, including a brand-name drug product. The pharmacist must maintain a record of any drug substitution. Florida law governing the Medicaid program also requires generic substitution of brand-name drug products.<sup>5</sup>

### **Pharmacy Practice**

Chapter 465, F.S., governs the practice of the profession of pharmacy. The Board of Pharmacy within the Department of Health is authorized to adopt rules for duties conferred upon it under the pharmacy practice act. Section 465.003, F.S., defines the “practice of the profession of

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<sup>1</sup> See the website for the Epilepsy Therapy Development Project at <<http://www.epilepsy.com/>> (Last visited on March 18, 2007).

<sup>2</sup> See “Battling Epilepsy, and Its Stigma” by Aliyah Baruchin, The New York Times, (February 20, 2007).

<sup>3</sup> See s. 385.207, F.S.

<sup>4</sup> See s. 465.025, F.S.

<sup>5</sup> See s. 409.908(14), F.S., which requires Medicaid providers to dispense generic drugs if available at a lower cost and the Agency for Health Care Administration has not determined that the branded product is more cost-effective, unless the prescriber has requested and received approval to require the branded product. See also 42 CFR 447.331(c) relating to the Medicaid program, which provides that certain payment limitations do not apply if “a physician certifies in *his or her own handwriting* that a specific brand is medically necessary for a particular patient.”

pharmacy” to include compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent and proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services.

### **III. Effect of Proposed Changes:**

The bill amends the requirements for generic substitution for brand-name prescription drugs to prohibit a Florida-licensed pharmacist from “interchanging” or substituting an antiepileptic drug or formulation of an antiepileptic drug, brand or generic, for the treatment of seizures or epilepsy without prior notification of and the signed, informed consent to such interchange from the prescribing physician and the patient or the patient’s parent, legal guardian, or spouse.

For purposes of the prohibition, the generic substitution law in s. 465.025, F.S., is amended to define relevant terms. “Antiepileptic drug” is defined to mean any drug prescribed for the treatment of epilepsy or any drug used to treat or prevent seizures. “Epilepsy” means a neurological condition characterized by recurrent seizures. “Interchange” means the substitution of one version of the same antiepileptic therapeutic product, including a generic version for the prescribed brand version, a brand version for the prescribed generic version, a generic version by a manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed antiepileptic drug, or a different antiepileptic therapeutic drug product for the antiepileptic product originally prescribed. “Seizure” is defined to mean an acute clinical change that is secondary to a brief disturbance in the electrical activity of the brain.

The generic substitution law in s. 465.025, F.S., is also amended to create an exception for antiepileptic drugs to its requirements for a Florida-licensed pharmacist to substitute a generic drug for a brand name drug when the pharmacist receives a prescription for a brand name drug.

The bill amends s. 440.13, F.S., relating to medical services and supplies under the Workers’ Compensation Law, and s. 465.0251, F.S., relating to generic drugs to conform statutory cross-references.

The effective date of the bill is upon the bill 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 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, Section 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:**

Persons with epilepsy may benefit in having access to the specific drug prescribed to treat their condition.

**C. Government Sector Impact:**

According to the Agency for Health Care Administration, costs to the Florida Medicaid program could exceed \$52 million annually if this bill becomes law. The Agency for Health Care Administration estimates that cost increases for private commercial health plans will be comparable and could exceed \$300 million or more annually. This expenditure may be offset by decreased morbidity and any other complications resulting in expenditures to treat persons with epilepsy such as additional physician services or hospitalization.

The Department of Health, which enforces pharmacy regulations in Florida, will incur additional costs to implement the bill.

**VI. Technical Deficiencies:**

On page 4, line 8, the term “prescribing physician” should be changed to “prescribing practitioner” to reflect the fact that licensed health care practitioners other than medical physicians may prescribe antiepileptic drugs.

**VII. Related Issues:**

The bill requires a pharmacist to obtain the signed, informed consent of a “prescribing physician before “interchanging” or substituting an antiepileptic drug. It is unclear under what circumstances the pharmacist is going to be able to obtain both the signature and “informed consent” of the physician. The requirement for a signature may impose an impediment to electronic prescribing or to a recommendation by a pharmacist in her or his professional judgment to the prescribing practitioner.

## **VIII. Summary of Amendments:**

### **Barcode 281612 by Health Regulation:**

The amendment changes “prescribing physician” to “prescribing practitioner” to reflect the fact that licensed health care practitioners other than medical physicians may prescribe antiepileptic drugs.

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This Senate Professional Staff Analysis does not reflect the intent or official position of the bill’s introducer or the Florida Senate.

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