HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 849 Anti-Epileptic Drugs
SPONSOR(S): Garcia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Innovation	9 Y, 0 N	Ciccone	Calamas
2) Healthcare Council			
3)			
4)			
5)			

SUMMARY ANALYSIS

House Bill 849 prohibits Florida licensed pharmacists from interchanging an anti-epileptic drug, brand or generic, to treat seizures or epilepsy without the prior notification and signed informed consent of the interchange from the prescribing physician and patient, or patient's parent, legal guardian, or spouse of the patient's parent or legal guardian.

The bill provides a fiscal impact.

The bill is effective upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited government – the bill prohibits Florida licensed pharmacists from interchanging an anti-epileptic drug to treat seizures or epilepsy without the prior notification and signed informed consent from the prescribing physician and patient, or patient's parent, legal guardian, or spouse of the patient's parent or legal guardian.

Empower families – the bill provides the patient with an active part in the decision making process to fill the patient's prescription by requiring prior notification and signed informed consent. In this way, the patient is provided a choice in the medication to treat his or her health care needs.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Epilepsy

Epilepsy is a brain disorder in which clusters of nerve cells, or neurons, in the brain sometimes signal abnormally. In epilepsy, the normal pattern of neuronal activity becomes disturbed, causing strange sensations, emotions, and behavior or sometimes convulsions, muscle spasms, and loss of consciousness.[1] Approximately fifty million people are living with epilepsy in the world and greater than 2.7 million in the United States. Medication controls seizures for the majority of patients. Seventy percent of people with epilepsy can be expected to enter remission, defined as five years with seizures on medication.[2]

Section 385.207, F.S., directs the Department of Health to administer a program to provide assistance to persons with epilepsy and promote programs regarding case management, diagnosis, care and treatment of persons affected by this disease, including required pharmaceuticals, medical procedures, and techniques which will have a positive effect in the care and treatment of persons with epilepsy.

Generic Drug Substitution

Section 465.025, F.S., 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. 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 his or her 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.

With regard to the Medicaid Program, section 409.908(14), F.S., requires that Medicaid providers 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.

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[1] See www.nind/epilepsy.org. National Institute of Neurological Disorders, Epilepsy Information Page.
[2] See www.epilepsyfoundation.org. Epilepsy and Seizure Statistics

Pharmacy Practice

Chapter 465, F.S., governs the practice of the pharmacy profession. 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 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.

Effect of Proposed Changes

The bill prohibits Florida licensed pharmacists from interchanging an anti-epileptic drug, brand or generic, to treat seizures or epilepsy without prior notification and signed informed consent of the interchange from the prescribing physician and patient, or patient's parent, legal guardian, or spouse of the patient's parent or legal guardian. The effect of this proposal would be to disallow pharmacists' current practice of automatically dispensing generic or brand name products when available for epilepsy or anti-seizure drugs.

C. SECTION DIRECTORY:

Section 1. Creates s. 465.0245, F.S.; relating to anti-epileptic drug interchange prohibition.

Section 2. Provides an effective date upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Refer to Fiscal Comments.

2. Expenditures:

   Refer to Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   N/A

2. Expenditures:

   Locally funded health care programs will likely experience increased costs.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private sector health care plans will likely experience increased costs.

D. FISCAL COMMENTS:

According to the Agency for Health Care Administration the estimated fiscal impact at current claim levels for the current Medicaid fee-for-service population would be $52 million annually. This estimate does not include the costs to health plans or plan rates paid by Medicaid for managed care. The increased recurring amount would be the cost of reimbursing Medicaid fee-for-service prescriptions for

all anticonvulsants, Diazepam and Lorazepam at brand pricing levels and assuming no generic use. The estimate does not consider any potential drug manufacturer rebates.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

It is important to note that House Bill 849 does not promote brand name drugs over generics. Instead, the expressed intent of House Bill 849 is to provide a better system of checks and balances in which the physician, patient and pharmacist all work together toward the goal of seizure management and thus improved quality of life for persons with epilepsy. The benefits of providing patients with a choice in the medication prescribed for their treatment is the primary reason behind this initiative.

Drug formulation differences can cause a person with epilepsy to experience breakthrough seizures. These seizures can result in unnecessary emergency room visits, lost wages and even a compromised ability to drive

The potential cost savings associated with an unmanaged automatic drug substitution policy of seizure control medications may be offset by the additional costs expected with potential breakthrough seizures, such as additional office visits, additional lab tests, and the likelihood of increased emergency room visits or extended periods of hospitalizations.

I strongly disagree with the Agency for Health Care Administration's fiscal analysis, which assumes full use--everyone taking generic drugs will start taking brand name drugs and that is not the case or what my bill does.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 27, 2007, the Health Innovation Committee adopted one favorable amendment. This amendment:

- Revised the effective date as upon becoming law, subject to a specific appropriation.

The bill was reported favorably with one favorable amendment.