F I S C A L I M P A C T R E P O R T

SPONSOR Culbert **ORIGINAL DATE** 2/14/07 **LAST UPDATED** **HB** 1020

SHORT TITLE Use of Certain Drugs Without Consent **SB**

ANALYST C. Sanchez

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY07	**FY08**		
	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

Relates to HB 566 Generic Drug Prescription Authorization

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY07	FY08	FY09	3 Year Total Cost	Recurring or Non-Rec	Fund Affected
Total	$10.0	$10.0	$10.0	$30.0	Recurring	Pharmacy

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Responses Received From
Medical Board (MB)
Regulation and Licensing Department (RLD)

SUMMARY

Synopsis of Bill

House Bill 1020 adds a new section to the Drug Product Selection Act (NMSA 26-3-1 to 26-3-3) that prohibits a pharmacist from substituting a therapeutically equivalent anti-epileptic drug for the one prescribed by the practitioner unless the practitioner and the patient (or the patient's legal representative) has given written (informed) consent.

The new section of the Bill:

- In paragraph “A” adds a definition for; “anti-epileptic drug” means a drug prescribed for the treatment of epilepsy or to treat or prevent seizures,
- Adds a definition for; “epilepsy” means a neurological condition characterized by recurrent seizures,
- Adds a definition for; “interchange” "interchange" means the substitution of one version of the same anti-epileptic therapeutic product, including a generic version, for the prescribed brand, a brand version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, a different formulation of the prescribed anti-epileptic drug or a different anti-epileptic therapeutic drug product for the anti-epileptic product originally prescribed,
- Adds a definition for; "seizures" means acute clinical change secondary to brief disturbances in the electrical activity of the brain.

In paragraph “B” sets the following restrictions in place: A pharmacist shall not interchange an anti-epileptic drug or formulation of an anti-epileptic drug, whether brand or generic, for the treatment of epilepsy or seizures without the prior written informed consent of the prescribing physician and the person, or the person's legal representative, for whom the anti-epileptic drug was prescribed

FISCAL IMPLICATIONS

The Board will conduct an estimated 10 investigations each year at an average cost of $1,000 each based on the cost of the investigation and the administrative prosecution.

SIGNIFICANT ISSUES

The current Drug Product Selection Act does not mandate substitution. It allows a practitioner to prevent drug substitution by writing, “do not substitute” or “do not sub” on the prescription. In order for a pharmacist to substitute a generic version of the drug prescribed by the practitioner it must appear on the FDA’s list of “Approved Products and Therapeutic Equivalents” as an approved therapeutic equivalent.

Third parties (insurance providers, PBMs) do require the substitution of a brand drug with a therapeutic equivalent as part of cost saving measures. They do allow the Brand that was prescribed, to be dispensed when the practitioner has sought and obtained prior authorization from the insurance carrier. Medicaid operates the same way where a practitioner must indicate the Brand is medically necessary in order to prevent substitution.

The Federal Food and Drug Administration compiles a publication of approved drug products and drug therapeutic equivalents. “The publication, ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal® Tablets and Librax® Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective

approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the List contains therapeutic equivalence evaluations for approved multisource prescription drug products."(FDA.Gov/cder) The electronic version is updated daily. The FDA evaluates all the required research (clinical trials, bio-equivalence, bio-availability, identity, strength, quality, purity, and potency of the product etc) in its assessment and approval of a New Drug Application or an Abbreviated New Drug Application.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

Relates to HB566 – Generic Drug Prescription Authorization, which would amend the Drug Product Selection Act to require personal authorization from the prescribing physician for a pharmacist to interchange any medication.

TECHNICAL ISSUES

The Bill does not define or indicate what "informed consent" is or what elements it consists of. This places the interpretation of that term in civil courts.

OTHER SUBSTANTIVE ISSUES

HB 1020 would enhance protections for patient health and safety by requiring that both the patient and the patient's treating physician consent to any anti-epileptic medication substitutions. This requirement may also slow prescription processing time.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Pharmacists may be able to interchange one anti-epileptic drug for another without the informed consent of the patient and treating physician.

CS/nt