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FISCAL IMPACT REPORT

SPONSOR _	Heaton	DATE TYPED	2/22/05	HB	697
SHORT TITLE Therapeutic Intercha		nge of Prescription	Drugs	SB	

ANALYST Hanika-Ortiz

APPROPRIATION

Appropriation Contained		Estimated Add	litional Impact	Recurring or Non-Rec	Fund Affected
FY05	FY06	FY05	FY06		
	See Narrative			Recurring	

SOURCES OF INFORMATION LFC Files

<u>Responses Received From</u> New Mexico Pharmacy Board (NMPB) Health Policy Commission (HPC) Department of Health (DOH)

SUMMARY

Synopsis of Bill

HB 697 enacts a newly created section to the Drug Product Selection Act allowing a pharmacist to exchange a therapeutic alternate drug for the prescribed drug after receiving either verbal or written authorization.

Significant Issues

The NMPB notes that when a pharmacist contacts a prescriber the first time a drug is ordered that is not on the formulary, the practitioner allows the pharmacist to substitute with a therapeutic alternative. Under current law the pharmacist has to contact the practitioner each time this occurs. Many practitioners request to leave a letter or verbal notification on file at the pharmacy authorizing such substitutions for the future. The NMPB believe this bill would expedite the process and still maintain patient safety.

PERFORMANCE IMPLICATIONS

The American Medical Association (AMA) accepts the concept of therapeutic *interchange*; i.e., the authorized exchange of therapeutic alternates in accordance with previously established and medical staff-approved written guidelines or protocols, within a drug formulary system. The AMA clearly differentiates therapeutic interchange from therapeutic *substitution*; i.e. the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber, and reaffirms its strong opposition to therapeutic substitution in any patient care setting. HB697 incorporates the AMA definition of "therapeutic interchange" and requires prior authorization by the prescribing practitioner.

The American Society of Health-System Pharmacists also supports therapeutic interchange if there is "timely communication between prescriber and pharmacist in the development of programs." Likewise, the American College of Clinical Pharmacy supports such interchange when there is collaboration between pharmacists and physicians "to design protocols that provide patients with the best possible care at the lowest possible cost."

FISCAL IMPLICATIONS

The HPC reports that in addition to other cost-management strategies such as purchasing pools, state-negotiated discounts, pharmacy assistance programs and reimportation of pharmaceuticals, New Mexico allows the substitution of drug products that are chemically identical in strength, concentration, dosage form, and route of administration to the drug product, that is, a brand name product for a generic copy. The FDA has found that patients using generic drugs experience reductions of up to 52% in the daily costs of their medications.

Opponents to substitution maintain that such methods restrict access to beneficial drugs, confuse drug efficacy and treatment effectiveness, and may not be appropriate for certain populations and individuals.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

Conflicts with SB 488 which amends the Drug Product Selection Act, proposes a Therapeutic Equivalents Board, authorizes the substitution of 'equivalent' drugs, and requires the immediate notification of the patient and provider.

Relates to SB 588 which creates a Pharmacy and Therapeutics Committee to conduct drug utilization review, make recommendations to the HSD, and requires the use of findings in certain circumstances.

Relates to SJM 8 which creates a task force to study importing prescription drugs from Canada and Mexico.

TECHNICAL ISSUES

The bill is unclear if telephonic communication is required to be documented in a log as to time, date, practitioner name, and authorized person receiving information.

There is no provision in the bill to recommend continuing education activities for pharmacists.

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Some limitation on the use of therapeutic interchange might be included. The current AMA Policy states "switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen should be discouraged."

Although HB697 specifies that the authorized "therapeutic alternate drug" must be exchanged within the context of a formulary system or preferred drug list that has been established "in accordance with previously approved written guidelines or protocols", it does not set a standard for such guidelines or protocols or refer to any specific approving public or private body.

SUBSTANTIVE ISSUES

The HPC provides the following information on the use of therapeutic interchange:

Like drug formularies, almost all hospitals have therapeutic interchange programs as a means to reduce the complexity of drug therapy in the hospital, to address the problem of numerous "me-too" drugs in many drug classes, and to help control escalating drug costs. As long as such programs are part of a formal drug formulary system that is overseen by the institution's medical staff, the AMA believes there are adequate controls in place to ensure patient safety.

The AMA reports "hospital-based therapeutic interchange programs can substantially reduce costs to an institution without negatively affecting patient care most of the time. However, because failures can occur, therapeutic interchange policies should be implemented cautiously and evaluated systematically."

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL?

The present day practice for substituting "generic drugs" and developing formularies by state departments and health plans will continue.

AHO/lg