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## FISCAL IMPACT REPORT

ORIGINAL DATE 02/02/09

SPONSOR Heaton LAST UPDATED 02/10/09 HB 282/aHGAC

SHORT TITLE Therapeutic Interchange of Alternate Drugs SB \_\_\_\_\_

ANALYST C. Sanchez

### APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY09	FY10		
	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

### SOURCES OF INFORMATION

LFC Files

#### Responses Received From

Regulation and Licensing Department (RLD)

Medical Board (MB)

NM Health Policy Commission (MNHPC)

### SUMMARY

#### Synopsis of HGAC Amendment

The House Health and Government Affairs Committee amendment to HB 282 expands the authority of valid prescriptions from “written” to “written and authorized”. It also expands the definition of "therapeutic interchange" to include the requirement for informed consent of the patient.

#### Synopsis of Original Bill

House Bill 282 proposes a new section to the Drug Product Selection Act entitled “Therapeutic Interchange of Prescription Drug Authorized.” This amendment determines that upon receipt of a written prescription by a licensed practitioner, a pharmacist has the ability to exchange a therapeutic alternate drug in accordance with prior authorization from the prescribing practitioner.

This bill defines the following terms:

- “Prior Authorization” – refers to a written, an electronic, or a telephonic authorization that allows a pharmacist to execute a therapeutic interchange of a drug for a prescription that is being presented.
- “Therapeutic Alternate Drug” – refers to a drug product with a different chemical structure than the prescribed drug, but it is from the same pharmacological or therapeutic class.
- “Therapeutic Interchange” – refers to the authorized exchange of a therapeutic alternate drug within a formulary system or preferred drug list.

## **FISCAL IMPLICATIONS**

There will be minimal impact on the Regulation and Licensing Department. The Board and Commissions program would probably have two or three investigations each year that might involve therapeutic exchange complaints.

## **SIGNIFICANT ISSUES**

Health plans usually require health care practitioners to prescribe medications from a select list of medications (drug formulary) that have been approved for use by that plans pharmacy and therapeutics committee or similar entity. Every plan has a different drug formulary meaning the prescription drugs listed on these formularies varies significantly from plan to plan. Practitioners frequently do not have the time to become familiar w/ all the continuing formulary changes/deletions or additions. Health plans usually limit the number of drug selections within a pharmacological class. If a practitioner prescribes a drug that is not listed on the formulary then under current state law the pharmacist must contact the prescriber to obtain a new prescription for the prescription drug that is on the list. When a pharmacist contacts a prescriber the first time the prescriber orders a drug that is not on formulary, the practitioner either authorizes the change or initiates a prior authorization request to the insurance company requesting the patient be reimbursed for a non-formulary drug. Pharmacists, under current law, have to contact the practitioner each time this occurs. Many physicians have asked for the ability to leave a letter or verbal notification on file at the pharmacy authorizing such substitutions (according to the health plan’s drug formulary) in the future.

The State has a law (NMSA 26-3-1 et seq.) allowing the substitution of therapeutically equivalent drugs. Those drugs have been determined to have the same active ingredients and will be delivered/absorbed in an equivalent amount of the active drug. The drug must be in the same dosage form to be considered therapeutically equivalent. The FDA states: “drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.”

Therapeutic interchange is known as: the practice of switching or dispensing a “therapeutic alternate drug” that is chemically distinct but therapeutically similar in terms of its efficacy, safety, and tolerability profiles. The goal of therapeutic interchange is to achieve an improved or neutral outcome with the new agent while reducing overall treatment costs.

Therapeutic interchange, switching to a therapeutic alternate drug, has been safely practiced in hospitals and other closed health care systems for years. These programs involve drug switches within drug classes, such as angiotensin-converting enzyme (ACE) inhibitors, proton pump inhibitors (PPIs), HMG-CoA reductase inhibitors, (and selective serotonin reuptake inhibitors (SSRIs), antibiotics based on microbial coverage and generally to drugs that use the same routes of administration.

### **ADMINISTRATIVE IMPLICATIONS**

The Board of Pharmacy will need to adopt clarifying language for what a formulary system or preferred drug list is.

### **CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP**

HB282 relates to HB192 (Prescription Drug Prior Authorization Process), HB232 (Prescription Privacy Act), HB233 (State Prescription Drug Price Information), HB243 (Prescription Drug Re-Importation), SB40 (Prescription Drug Donation), SB82 (Permit Re-dispensation of Unused Prescriptions), SB129 (Prescription Drug Retail Price Disclosure), and SJM6 (UNM Prescription Drug Task Force).

### **TECHNICAL ISSUES**

Paragraph A. The language “prescription written” should be changed to “prescription written or authorized by a licensed practitioner” to allow the therapeutic interchange on both verbal/electronic/faxed/and written prescriptions.

### **OTHER SUBSTANTIVE ISSUES**

According to the Minnesota RxConnect, therapeutic alternative medications are chemically different but have similar therapeutic effects. For example, acetaminophen and aspirin are different chemicals but because both are used for pain and fever, they may be used as therapeutic alternatives.

In Arizona, the LifeWise Health Plan of Arizona created the Therapeutic Alternative Program. This is a voluntary program designed to promote cost-effective generic drug use and minimize pharmacy expenses for our members. Medical experts have determined that many generic alternatives can have the same clinical benefits as more expensive, heavily marketed, brand-name drugs.

In 2008, the American Academy of Family Physicians strongly opposed any legislative or regulatory effort at the state or federal level to permit therapeutic substitution.

The NM Medical Board believes this is a sound bill that is properly justified and protects all participants.

### **WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL**

The consequences of not enacting this bill will prevent pharmacists from having the ability to interchange a therapeutic alternate drug.