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

SPONSOR Heaton **ORIGINAL DATE** 1/20/2006 **LAST UPDATED** 2/7/2006 **HB** 34/aHCPAC

SHORT TITLE Interchange of Therapeutic Alternate Drugs **SB**

ANALYST McOlash

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY06	**FY07**		
NFI	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files
www.fda.gov/cder/drugsatfda/glossary.htm
https://physician.express-scripts.com/esi_md/info/faq/1,11259,,00.html

SUMMARY

Synopsis of HCPAC Amendment

The House Consumer and Public Affairs Committee amendment does the following:

A. Upon receipt of a prescription written by a practitioner who may prescribe drugs, a pharmacist may therapeutic interchange of a prescription drug with a therapeutically alternate drug in order to comply with a preferred drug list or formulary, in accordance with prior authorization granted by the prescribing practitioner (page 1, line 23) and after consultation with the patient or the patient's representative. The pharmacist must notify the prescribing practitioner of the therapeutically alternate drug that was dispensed" (page 1, line 24).

"C. The therapeutic interchange of a prescription drug pursuant to Subsection A of this section shall not be construed in any way to constitute permitted product selection for the purposes of Subsection B of Section 27-2-16 NMSA 1978 unless drug product selection is otherwise permitted by that subsection upon such therapeutic exchange."". (page 2, line 17).

Synopsis of Original Bill

House Bill 34 enacts a new section to the Drug Product Selection Act that allows pharmacies to dispense "therapeutic alternative drugs" upon prior authorization from the prescribing practitioner.

SIGNIFICANT ISSUES

Therapeutic alternative programs are typically based upon lists from pharmacies, states, or other agencies. For example, Express Scripts indicates that:

> Alternative, or therapeutic alternative, drugs are drugs that can be substituted for other drugs. Many times, therapeutic alternatives are selected because they are equally effective as the originally prescribed drug, but they cost less or are the preferred drug on the prescription benefits formulary.
>
> For example, "antihistamines" is an example of a drug class. Numerous drugs such as Claritin, Allegra, Zyrtec, and Clarinex are contained in the antihistamine drug class. These antihistamines are generally thought to be equally effective for treating allergies. So, if Claritin is originally prescribed to treat a patient's allergies but it is not covered by the prescription drug formulary, an equally effective therapeutic alternative such as Allegra, Zyrtec, or Clarinex may be chosen to substitute for Claritin.

The federal FDA defines **therapeutic equivalence** as follows:

> Drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product. Drug products are considered to be therapeutically equivalent **only** if they meet these criteria:
>
> - they are pharmaceutical equivalents (contain the same active ingredient(s); dosage form and route of administration; and strength.)
> - they are assigned by FDA the same therapeutic equivalence codes . . .
>
> The coding system for therapeutic equivalence evaluations allows users to determine whether FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide additional information on the basis of FDA's evaluations.

OTHER SUBSTANTIVE ISSUES

House Bill 34 uses the term "therapeutic alternate" and "therapeutic interchange." Generally, Therapeutic Interchange Programs are programs that allow pharmacists to automatically substitute a drug that is preferred on a preferred drug list for a nonpreferred drug when a prescription is

filled. Drug interchange programs are often created to save money on drug costs while still providing safe, effective, and less costly drugs.

TECHNICAL ISSUE

The bill contains no effective date. If passed by the Legislature, the provisions become effective 90 days after it is signed by the governor.

POSSIBLE QUESTIONS

House Bill 34 leaves the determination of "therapeutically alternative drug" up to the prescribing practitioner and the pharmacist, or perhaps, the drug benefit providers.

Would consumers prefer therapeutic equivalents defined by the FDA or therapeutic alternatives as determined by health care providers?

BMC/yr:nt