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

SPONSOR Sanchez, B. **DATE TYPED** 02/07/04 **HB**

SHORT TITLE Drug & Device Info In English & Spanish **SB** 124

ANALYST Geisler

APPROPRIATION

Appropriation Contained		Estimated Additional Impact		Recurring or Non-Rec	Fund Affected
FY04	FY05	FY04	FY05		
			Unknown		

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

Regulation and Licensing Department Board of Pharmacy (PB)

SUMMARY

Synopsis of Bill

Information provided on the outside container or wrapper of a prescription (dangerous drugs) or device relating to the drug's or device's efficacy, safety, suitability, side effects or interactions shall be provided in Spanish and English to be labeled with side effects on the outside of each container or wrapper in English and Spanish.

Significant Issues

PB provides that there is not ample space on the outside of a prescriptions container to attach a label that would list all of these effects and side effects. The PB provides alternatives to accomplish the objectives of the bill below under Alternatives and Amendments.

FISCAL IMPLICATIONS

PB provides that it is possible that the cost of dispensing prescription drugs from state hospitals and pharmacies will increase due to additional requirements and programming to implement printing of labels in both languages. It is possible that this could also apply to the private sector.

TECHNICAL ISSUES

The Board of Pharmacy does not license the dispensers of devices unless it is from a business that also handles dangerous (prescription) drugs. The legislature could require the dispensers of any device to have written supplemental information available for the public,. (See amendments)

The proposed changes to the Drug, Device, and Cosmetic Act should be place in NMSA 26-1-16B. (see amendments)

ALTERNATIVES

The New Mexico Board of Pharmacy could adopt regulations requiring supplemental information for dangerous drugs dispensed, by a pharmacy or licensed clinics, be available in English and Spanish.

Other states do require supplemental drug information but they do not specify English or Spanish.

AMENDMENTS

The Board of Pharmacy suggests two alternative amendments:

Option 1

The suggested underlined changes, to NMSA 26-1-16B, to require the availability of written supplemental drug information:

> **B.** Practitioners licensed in this state may prescribe, provide samples of and dispense any dangerous drug to a patient where there is a valid physician-patient relationship. A record of all such dispensing shall be kept showing the date the drug was dispensed and bearing the name and address of the patient to whom dispensed. It is the duty of every licensed physician, dentist, veterinarian, pharmacist or person holding a limited license issued under Subsection B of Section 61-11-14 NMSA 1978, when dispensing any dangerous drug, to mark on the dispensing container the name of the patient, the date dispensed, the name and address of the person dispensing the drug, the name and strength of the drug, expiration date where applicable, adequate directions for use and the prescription number when applicable. All official compendium requirements for the preservation, packaging, labeling and storage of dangerous drugs are applicable where drugs are held for dispensing to the public, whether by a pharmacy, clinic, hospital or practitioner. Written supplemental drug information, that includes major drug-drug interactions, drug-food interactions, major side-effects, and proper use, shall be available to the public, in Spanish and English, from the dispensers of any dangerous drug.

The suggested addition to NMSA 26-1-3 Prohibited Acts, to require written supplemental device information:

26-1-3. Prohibited acts.

The following acts are prohibited:

K. the dispensing of any device with out having written information concerning major side effects and proper use in both Spanish and English, available to the public.

Option 2

New section of NMSA Drug, Device and Cosmetic Act

26-1-16.1 Dangerous Drug and Device Supplemental Information

A. The dispensers of any dangerous drug or device shall have written supplemental information available for the patient in Spanish and English. Such information shall contain:
    1. for a device; written information concerning major side effects, cautions for use, and proper use.
    2. for a dangerous drug; major drug-drug interactions, major drug-food interactions, major side-effects, missed dose, cautions for use, and proper use.

GGG/dm