ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2926

with committee amendments

STATE OF NEW JERSEY

DATED: June 12, 1997

The Assembly Health Committee reports favorably and with committee amendments Assembly Bill No. 2926.

As amended by the committee, this bill is intended to protect the interests and safety of patients who are prescribed narrow therapeutic range (NTR) drugs.

Accordingly, this bill exempts designated NTR drugs from mandatory substitution pursuant to the "Prescription Drug Price and Quality Stabilization Act," P.L.1977, c.240 (C.24:6E-1 et seq.), but allows substitution if the prescriber gives informed consent for the substitution. The bill authorizes the Drug Utilization Review Council in the Department of Health and Senior Services to establish a list of NTR drugs using the criteria set forth in this bill. The drug formulation shall meet at least three of the following criteria: that the drug formulation meets the federal Food and Drug Administration criteria for narrow therapeutic range as provided in 21 C.F.R. 320.33, unless the drug formulation was approved for marketing by the federal Food and Drug Administration prior to 1938; that the drug formulation is used to treat a critical acute or chronic condition; that the drug formulation is associated with the risk of toxic reactions, complex drug-drug interactions or steep dose response curves; that the drug formulation has highly individualized dosing requiring continuing dose supervision by the prescriber to ensure its safe use; or that there is a competent medical determination that a lack of bioequivalency could have a serious adverse effect in the treatment or prevention of a serious disease or medical condition. The council may adopt additional criteria to use in determining whether a drug formulation shall be included on its list of NTR drug formulations, and shall adopt the list, pursuant to the "Administrative Procedure Act."

The bill provides that a pharmaceutical manufacturer may apply to the council to have one of its drug formulations added to the list established by the council. Also, the bill provides that the council shall make available, upon request, the complete list of NTR drug formulations designated by the council as subject to the provisions of the bill.

The Drug Utilization Review Council also shall adopt, by regulation, a list of interchangeable drug products for the designated NTR drug formulations that shall be permitted for substitution by a pharmacist in the event that a prescriber gives informed consent for substitution or the original prescription is written for the drug formulation's generic name.

In order to ensure that the most appropriate drug product is dispensed in the event that the pharmacist substitutes the drug formulation pursuant to the provisions of this bill, the bill provides that the selection of the interchangeable drug product shall be the responsibility of the pharmacist dispensing the product, and that no employer, health insurance carrier, including a health maintenance organization or other managed care entity, or agent thereof, or other person may require the dispensing of a particular drug product which in the professional judgment of the dispensing pharmacist is not in the best interest of the patient.

The provisions of this bill apply to any pharmacist subject to the provisions of the "Prescription Drug Price and Quality Stabilization Act."

The penalty for violating the provisions of the bill is a written warning from the Board of Pharmacy for a first offense, and a penalty of not less than $100 for a second offense, and not less than $200 for each subsequent offense.

NTR drugs are widely used for the treatment of a number of acute or chronic medical conditions, including heart attack, organ transplants, stroke, asthma, osteoporosis, epilepsy and depression. Drugs commonly considered to have a narrow therapeutic range include: carbamazepine, conjugated estrogens, digoxin, levothyroxine sodium, phenytoin sodium, cyclosporine, theophylline and warfarin sodium.

These drugs are designated as having a narrow therapeutic range because of the narrow margin that exists between patient benefit and patient risk. NTR drugs have highly individualized dosing, requiring close, careful and skilled patient monitoring to ensure that the level of the prescribed drug in the patient's blood stays within the narrow therapeutic range, or window, appropriate for that medication. A change in formulations of a NTR drug has the potential of causing the dosage to vary outside the therapeutic window, exposing the patient to the risks associated with too low or too high a dosage. Changes in formulation can include changing from a brand name formulation to a generic formulation or another brand name formulation, or from one generic formulation to another, or from a generic formulation to a brand name formulation.

This bill will prohibit any change from the formulation upon which the patient was stabilized, to any other formulation, without the knowledge and consent of the prescriber of the drug.

The committee amendments:

- revise the language in subsection d. of section 1 regarding the criteria to be used by the Drug Utilization Review Council in determining whether a drug formulation shall be included on its list of NTR drug formulations;
- permit the Drug Utilization Review Council to adopt, pursuant to the "Administrative Procedure Act," additional criteria beyond those specified in subsection d. of section 1 to use in determining whether a drug formulation shall be included on its list of NTR drug formulations;
- increase from 90 to 180 days the time period after the effective date of this bill for the Drug Utilization Review Council to establish its list of NTR drug formulations;
- provide that, in the event a pharmacist substitutes a drug formulation pursuant to the provisions of this bill, no employer, health insurance carrier, including a health maintenance organization or other managed care entity, or agent thereof, or other person may require the dispensing of a particular drug product which in the professional judgment of the dispensing pharmacist is not in the best interest of the patient;
- exempt from the provisions of this bill, a licensed inpatient health care facility with respect to a patient admitted to the facility who was being treated with a narrow therapeutic range drug at the time of admission; and
- revise the penalties for violating the provisions of the bill to a written warning from the Board of Pharmacy for a first offense, and a penalty of not less than $100 for a second offense, and not less than $200 for each subsequent offense.