# ASSEMBLY, No. 2926

# STATE OF NEW JERSEY

INTRODUCED MAY 5, 1997

**By Assemblywoman MURPHY and**
**Assemblyman DiGAETANO**

**AN ACT** concerning narrow therapeutic range drugs and supplementing and amending P.L.1977, c.240.

**BE IT ENACTED** *by the Senate and General Assembly of the State of New Jersey:*

1. (New section) a. Notwithstanding the provisions of any law to the contrary, if any of the narrow therapeutic range drug formulations designated by the Drug Utilization Review Council pursuant to this section is prescribed by its brand name, a different brand name or the drug's generic name, the prescribed drug formulation or refills thereof shall not be substituted by a pharmacist without the informed consent of the prescriber. The pharmacist shall record in his record of the prescription the date that the informed consent was given.

In the event the pharmacist substitutes the drug formulation pursuant to the provisions of this section, the selection of the interchangeable drug product shall be the responsibility of the pharmacist dispensing the product, subject to the provisions of subsection f. of this section, and no employer, agent 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.

b. The provisions of this section shall apply to any pharmacist subject to the provisions of P.L.1977, c.240 (C.24:6E-1 et seq.) and to 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.

c. The Drug Utilization Review Council shall, within 90 days of the effective date of this act, establish a list of narrow therapeutic range drug formulations that the council has selected pursuant to the criteria set forth in subsection d. of this section.

**EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and intended to be omitted in the law.**

**Matter underlined thus is new matter.**

The council shall adopt the list of narrow therapeutic range formulations pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.).

d. The Drug Utilization Review Council shall use the criteria set forth in this subsection to establish the list of narrow therapeutic range drug formulations. The drug formulation shall have been approved by the federal Food and Drug Administration after 1938, shall meet the Food and Drug Administration criteria for narrow therapeutic ratio as provided in 21 C.F.R. 320.33 and shall meet at least three of the following criteria: that the narrow therapeutic range drug formulation is used to treat a critical acute or chronic condition; that the narrow therapeutic range drug formulation is associated with the risk of toxic reactions, complex drug-drug interactions or steep dose response curves; that the narrow therapeutic range 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.

e. If a manufacturer of pharmaceutical products seeks to have one of its drug formulations added to the list adopted by the Drug Utilization Review Council pursuant to this section, the manufacturer shall apply to the council on a form and in a manner established by the council. The council shall make a determination as to whether the drug formulation should be added to the list within 120 days of receipt of a completed application, and notify the manufacturer of its determination. If the council determines that the drug formulation should be added to the list, the council shall provide public notice in the New Jersey Register of the addition to the list.

f. The Drug Utilization Review Council shall adopt, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C. 52:14B-1 et seq.), a list of interchangeable drug products for the designated narrow therapeutic range 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.

g. The Drug Utilization Review Council shall make available, upon request, the complete list of narrow therapeutic range drug formulations subject to the provisions of this section.

2. Section 12 of P.L.1977, c.240 (C.24:6E-11) is amended to read as follows:

12. Any person violating any provision of **[**this act**]** P.L.1977, c.240 (C.24:6E-1 et al.) or P.L. , c. (C. )(pending before the Legislature as this bill) shall be liable to a penalty of not less than

$100.00 for the first offense, and not less than $200.00 for each subsequent offense. Such penalty shall be collected and enforced by summary proceedings pursuant to the Penalty Enforcement Law (N.J.S.2A:58-1 et seq.). Process shall issue at the suit of the Board of Pharmacy or the Attorney General, and shall be either in the nature of a summons or warrant. In addition, the Board of Pharmacy may suspend or revoke the certificate of a registered pharmacist for violating any provision of **[**this act**]** P.L.1977, c.240 (C.24:6E-1 et al.) or P.L. , c. (C. )(pending before the Legislature as this bill). However, failure of the prescriber to utilize the form of prescription designated in section 8 of **[**this act**]** P.L.1977, c.240 (C.24:6E-1 et al.) shall not invalidate the prescription as written, if said prescription is otherwise valid.
(cf: P.L.1977, c. 240, s. 12)

3. This act shall take effect immediately.

STATEMENT

The purpose of this bill is 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," 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 have been approved by the federal Food and Drug Administration after 1938, shall meet the Food and Drug Administration criteria for narrow therapeutic ratio as provided in 21 C.F.R. 320.33 and shall meet at least three of the following criteria: that the narrow therapeutic range drug formulation is used to treat a critical acute or chronic condition; that the narrow therapeutic range drug formulation is associated with the risk of toxic reactions, complex drug-drug interactions or steep dose response curves; that the narrow therapeutic range 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 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, agent 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" and to a licensed inpatient health care facility with respect to a patient admitted to the facility who was being treated with a NTR drug at the time of admission.

The penalty for violating the provisions of the bill is at least $100 for the first offense and $200 for each subsequent offense. These penalties are the same as those provided for any violation of the "Prescription Drug Price and Quality Stabilization Act."

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.

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Provides for the exemption of certain narrow therapeutic range drugs from mandatory substitution requirements.