24:6E-1 et al.

LEGISLATIVE HISTORY CHECKLIST

NJSA: 24:6E-1 et al. ("Prescription Drug Price And Quality Stabilization Act")

LAWS OF: 1977 **CHAPTER** 240

BILL NO: A2021

Sponsor(s): Herman and others

Date Introduced: June 10, 1976

Committee: **Assembly:** Labor, Industry & Professions

Senate: Institutions, Health & Welfare

Amended during passage: Yes — Amendments during passage denoted by asterisks.

Date of Passage: **Assembly:** February 14, 1977

Senate: June 27, 1977

Date of Approval: September 29, 1977

Substituted for S222 (Attached)

Following statements are attached if available:

Sponsor statement: Yes

Committee statement: **Assembly** Yes

Senate Yes

Fiscal Note: Yes

Veto Message: No

Message on Signing: Yes

Following were printed:

Reports: No

Hearings: No

Hearings and reports on similar bills in 1974-75 session:

974.90 N222 1974b — N.J. Legislature. Assembly. Commerce, Industry, and Professions Committee. Public hearings . . . on A1257 (generic drug substitution), held June 3 and June 28, 1974.

(OVER)

Herman, Martin A. (Assemblyman)
Report in support of A1257 . . ., 1974.

N.J. Legislature. Assembly. Commerce, Industry and Professions Committee.
Public hearings . . . on A736, A1228, . . . A3273 (drug discounts and advertising by pharmacies), held May 22 and May 23, 1975.

CHAPTER 240 LAWS OF N.J. 1977
APPROVED 9-29-77

[SECOND OFFICIAL COPY REPRINT]

ASSEMBLY, No. 2021

STATE OF NEW JERSEY

INTRODUCED JUNE 10, 1976

By Assemblymen HERMAN and LEFANTE

Referred to Committee on Institutions, Health and Welfare

AN ACT concerning substitutions with respect to prescription drugs and the advertising of prescription drug prices, establishing a Drug Utilization Review Council in the Department of Health, amending R. S. 45:14–12 and making an appropriation therefor.

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

1. This act shall be known and may be cited as the "Prescription Drug Price and Quality Stabilization Act."

2. R. S. 45:14–12 is amended to read as follows:

45:14–12. The board may refuse an application for examination or may suspend or revoke the certificate of a registered pharmacist or a registered assistant pharmacist for any of the following causes: When the application or registration is shown to have been obtained by misrepresentation or fraudulent means or when the applicant or registrant is guilty of chronic or persistent inebriety, or has been adjudged guilty of violating any State or Federal law or any law of the District of Columbia or of any territory of the United States relating to the practice of pharmacy, or relating to the dispensing of drugs, or has been convicted of a crime involving moral turpitude, or has impersonated an applicant for registration before the board or has been convicted of knowingly, intentionally or fraudulently adulterating or causing to be adulterated drugs, chemicals or medicinal preparations or has sold or caused to be sold adulterated drugs, chemicals or medicinal preparations knowing, or having reason to know, that same were adulterated, or has procured or attempted to procure registration for another by misrepresentation or fraudulent means, and the board shall refuse an application for examination or suspend or revoke the certificate of a registered pharmacist or a registered assistant pharmacist when the applicant or registrant is shown to be addicted to the use

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

of narcotic drugs, or has been convicted of violating any law of this or any other state or of the United States relating to narcotic drugs or has been adjudicated an incompetent, or is shown to have any abnormal physical or mental condition which threatens the safety of persons to whom said applicant or registrant might sell or dispense prescriptions, drugs, chemicals, medicinal preparations or devices or for whom he might manufacture, prepare or package, or supervise the manufacturing, preparation or packaging of prescriptions, drugs, chemicals, medicinal preparations or devices. In addition, the board may refuse an application for examination or may suspend or revoke the certificate of a registered pharmacist or a registered assistant pharmacist upon proof satisfactory to the board that such registered pharmacist or such registered assistant pharmacist is guilty of grossly unprofessional conduct and the following acts are hereby declared to constitute grossly unprofessional conduct for the purpose of this act:

a. Paying rebates or entering into an agreement for payment of rebates to any physician, dentist or other person for the recommending of the services of any person.

b. The providing or causing to be provided to a physician, dentist, veterinarian or other persons authorized to prescribe, prescription blanks or forms bearing the pharmacist's or pharmacy's name, address or other means of identification.

c. [The promotion, direct or indirect, by any means, in any form and through any media of the prices for prescription drugs and narcotics or fees or for services relating thereto or any reference to the price of said drugs or prescriptions whether specifically or as a percentile of prevailing prices or by the use of the terms "cut rate," "discount," "bargain" or terms of similar connotation; but this shall not include the term nonprofit if such term is used by a nonprofit entity; and this paragraph shall not be construed or apply to have any effect with respect to sales made by pharmacists or pharmacies directly to physicians, dentists, veterinarians or other persons authorized to prescribe, or to hospitals, nursing homes, governmental agencies, or other institutions licensed under Title 30 of the Revised Statutes, as amended or to the advertising or issuance of trading stamps and similar devices in connection with the sale of said prescription drugs and narcotics.] *(Deleted by amendment.)*

d. The claiming of professional superiority in the compounding or filling of prescriptions or in any manner implying professional superiority which may reduce public confidence in the ability, character or integrity of other pharmacists.

e. Fostering the interest of one group of patients at the expense of another which compromises the quality or extent of professional services or facilities made available.

f. The distribution of premiums or rebates of any kind whatever in connection with the sale of drugs and medications provided, however, that trading stamps and similar devices shall not be considered to be rebates for the purposes of this chapter and provided further that discounts, premiums and rebates may be provided in connection with the sale of drugs and medications to any person who is 62 years of age or older. Before a certificate shall be refused, suspended or revoked, the accused person shall be furnished with a copy of the complaint and given a hearing before the board. Any person whose certificate is so suspended or revoked shall be deemed an unregistered person during the period of such suspension or revocation, and as such shall be subject to the penalties prescribed in this chapter, but such person may, at the discretion of the board, have his certificate reinstated at any time without an examination, upon application to the board. Any person to whom a certificate shall be denied by the board or whose certificate shall be suspended or revoked by the board shall have the right to review such action by appeal to the Appellate Division of the Superior Court in lieu of prerogative writ.

g. Advertising of prescription drug prices in a manner inconsistent with rules and regulations promulgated by the Director of the Division of Consumer Affairs; provided, however, no such advertising of any drug or substance *[*in Schedules II through V of the New Jersey Controlled Dangerous Substances Act, P. L. 1970, c. 226 (C. 24:21–1 et seq.)*]* *shall be authorized unless the Commissioner of Health shall have determined that such advertising is not harmful to public health, safety and welfare.*

3. (New section) In conformance with the Administrative Procedure Act, P. L. 1968, c. 410 (C. 52:14B–1 et seq.), the Director of the Division of Consumer Affairs shall promulgate rules and regulations governing the advertising of prescription drugs. Such rules and regulations shall include, but shall not be limited to, the following: (1) provisions governing the content of advertisements, including price quotations in conformance with usual and customary prescription amounts, dosage form, and services offered: (2) provisions prohibiting reference to the quality of a drug or its beneficial use; (3) provisions prohibiting the advertising for sale of a prescription drug at a retail price below the acquisition cost of the drug to the retail seller; (4) provisions governing the mandatory dissemination over the telephone of price information.

Such rules and regulations shall be consistent, insofar as practicable, with Federal laws and regulations concerning advertising of prescription drugs, and the director may make any such Federal law or regulation applicable to the advertising of prescription drugs within this State by rule or regulation.

4. (New section) It shall be unlawful for any individual, group or association to restrain, directly or indirectly, the flow of prescription drug price information to the public.

5. (New section) As used in this act unless the context clearly indicates otherwise:

a. "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

b. "Brand name" means the proprietary name assigned to a drug by the manufacturer thereof.

c. "Established name" with respect to a drug or ingredient thereof, means (1) the applicable official name designated pursuant to the Federal Food, Drug and Cosmetic Act (Title 21, USC 301 et seq.), or (2) if there is no such official name and such drug or ingredient is recognized in an official compendium, then the official title thereof in such compendium, except that where a drug or ingredient is recognized in the United States Pharmacopœia and in the Homeopathic Pharmacopœia under different official titles, the official title used in the United States Pharmacopœia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopœia shall apply, or (3) if neither (1) nor (2) is applicable, then the common or usual name, if any, of such drug or ingredient.

d. "Prescription" means an order for drugs or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals, and includes orders for drugs or medicines or combinations or mixtures thereof transmitted to pharmacists through word of mouth, telephone, telegraph or other means of communication by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

e. "Council" means the Drug Utilization Review Council.

f. "Chemical equivalents" means those drug products that contain the same amounts of the same therapeutically active ingredi-

ents in the same dosage forms and that meet present compendial standards.

g. "Reference drug product" means the product which is adopted by the council as the standard for other chemically equivalent drugs in terms of testing for the therapeutic equivalence. In all cases, the reference drug product shall be a currently marketed drug which is the subject of a full (not abbreviated) new drug application approved by the Federal Food and Drug Administration.

h. "Therapeutic equivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy or toxicity as their respective reference drug products.

i. "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

j. "Bioequivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability.

k. "Pharmaceutical equivalents" means those drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage form and that meet established standards.

l. "Interchangeable drug products" means pharmaceutical equivalents or bioequivalents that are determined to be therapeutic equivalents by the council.

m. "Present compendial standards" means the official standards for drug excipients and drug products listed in the latest revision of the United States Pharmacopœia (USP) and the National Formulary (NF).

6. (New section) There is hereby established in the Department of Health a Drug Utilization Review Council to consist of nine members appointed by the Governor, the Commissioner of Health and the Director of the Division of Consumer Affairs in the Department of Law and Public Safety or their designees. Of the members to be appointed by the Governor, two shall be licensed pharmacists, two shall be licensed physicians, who have pharmacological experience either through teaching, clinical research, or specific application of technical expertise, three shall be persons with professional scientific or research experience in pharmacology, who shall have specific expertise in the area of medical pharmacology and pharmaceutical agents, their interaction and potential toxicity, and two shall be members of the general public. The members

appointed by the Governor shall serve for a term of 5 years and until their successors have been appointed and qualified, but of those first appointed, two shall be appointed for a term of 2 years, two for a term of 3 years, two for a term of 4 years, and three for a term of 5 years.

Vacancies shall be filled in the same manner as the original appointments but only for the unexpired term. Council members shall serve without compensation but the members appointed by the Governor shall be entitled to reimbursement for any necessary and reasonable expenses incurred in the performance of their duties hereunder, provided that the amount of such reimbursement shall not exceed $1,000.00 annually.

The council shall meet annually and elect a chairman and secretary from among its members. The chairman and secretary shall serve for a term of 1 year. The council shall meet at such other times to carry out its functions and duties at the call of the chairman or a majority of its members. The council shall be entitled to employ such advisory, technical, and clerical personnel as it deems necessary within the limits of any appropriations made available therefor.

7. (New section) a. The council shall prepare a list of interchangeable drug products. This list shall be periodically reviewed in accordance with a schedule of and procedure for such review as shall be established by the council. In development of the list, distinctions shall be made when: (1) evidence of bioequivalence is considered critical and when it is not; (2) when levels of toxicity are considered critical and when they are not. The list may include interchangeable drug products used by the United States Government and its agencies, where the government or such agency has established the reliability of the drug products interchanged.

b. No drug products shall be included in such list until after a public hearing has been held thereon after at least 20 days notice. Such notice shall be mailed to every drug company that is authorized to do business in the State of New Jersey and to all persons who have made a timely request of the council for advance notice of its public hearings and shall be published in the New Jersey Register.

c. Manufacturers shall, upon the request of the council, be required to submit any information in their files that relates manufacturing processes and in vivo and in vitro tests to the bioavailability of any drug product. This requirement shall also apply to technical information obtained during research related to the development of new drug products, even when such information

bears only an indirect relationship to the final dosage form. The council shall not make such information public when there is a proprietary interest on the part of the manufacturer.

d. Any manufacturer of drug products shall have the right to request the council to evaluate its drug products for the purpose of inclusion on the list of interchangeable drug products, or to request that the council consider removal of any drug product from the list. Any such request shall be accompanied by such information as the council shall require, and any drug product involved shall be evaluated in the same manner and shall be subject to the same procedures and requirements as all other drug products evaluated by the council for inclusion on or removal from the list.

e. Prior to any drug product being approved by the council, the manufacturer shall be required to demonstrate that it has complied with the standards set forth in the Current Good Manufacturing Practices of Title 21 USC **or in such standards relating to drug manufacturing practices as may be promulgated by the Department of Health from time to time** and must show evidence of a satisfactory inspection by the Federal Food and Drug Administration **or the Department of Health**.

f. The council shall distribute copies of the list of interchangeable drug products and revisions thereof and additions thereto among physicians and other authorized prescribers and licensed pharmacists, and shall supply a copy to any person upon request, upon payment of the price established by the council.

g. The council shall be authorized to adopt reasonable rules and regulations, in accordance with the provisions of the Administrative Procedure Act, P. L. 1966, c. 410 (C. 54:14B-1 et seq.), to carry out its functions and duties under this act and to effectuate its purposes.

8. (New section) Every prescription blank shall be imprinted with the words, "substitution permissible**[,]**" **["substitution permissible—notify,"]** and "do not substitute" and shall contain space for the physician's or other authorized prescriber's initials next to the chosen option. Notwithstanding any other law, unless the physician or other authorized prescriber explicitly states that there shall be no substitution when transmitting an oral prescription or, in the case of a written prescription, indicates that there shall be no substitution by initialing the prescription blank next to "do not substitute," a different brand name or nonbrand name drug product of the same established name shall be dispensed by a pharmacist if such different brand name or nonbrand name

drug product shall reflect a lower cost to the consumer and is contained in the latest list of interchangeable drug products published by the council; provided, however, where the prescriber indicates "substitution permissible **[—notify]**, ***and requests the pharmacist to notify him of the substitution,***" the pharmacist shall transmit notice, either orally or by written notice to be mailed no later than the end of the business day, to the prescriber specifying the drug product actually dispensed and the name of the manufacturer thereof. However, no drug interchange shall be made unless a savings to the consumer results, and the **[full savings is passed]** ***pharmacist passes such savings*** on to the consumer ***in full by charging no more than the regular and customary retail price for the drug to be substituted***. **[When a drug is substituted from the list of interchangeable drug products, the consumer shall be advised that such drug is being substituted and the savings that will result and must approve such substitution.]** ***For prescriptions filled other than by mail, the consumer may, if a substitution is indicated and prior to having his prescription filled, request the pharmacist or his agent to inform him of the price savings that would result from substitution. If the consumer is not satisfied with said price savings he may, upon request, be dispensed the drug product prescribed by the physician. The pharmacist shall make a notation of such request upon the prescription blank.***

9. (New section) Notwithstanding any other law, where a different brand name or nonbrand name drug product of the same established name shall reflect a lower cost to the consumer and no drug product of such established name is included in the latest list of interchangeable drug products published by the council, or where in the professional judgment of the pharmacist there is no valid proof of efficacy for the drug product prescribed, or the pharmacist's patient profile record discloses drug sensitivity, allergies or adverse reactions to the drug product prescribed, or there exists a more appropriate drug product than the drug product prescribed, a different brand name or nonbrand name drug product shall be dispensed by the pharmacist, provided, however, that such action by a pharmacist shall be authorized only if in each case the pharmacist notifies the prescriber of the drug product to be dispensed and the name of the manufacturer thereof, and receives the approval of the prescriber to substitute such drug product for the drug product prescribed. The pharmacist shall be required to indicate on the prescription the date and time of the prescriber's approval and whether the approval was communicated orally or in writing.

10. (New section) If a nonbrand name drug product is dispensed, the pharmacist shall include on the label of such drug product dispensed pursuant to a prescription, the established name **[and]** ***or*** the name of the manufacturer, except where the prescriber indicates to the contrary on the prescription.

11. (New section) Every pharmacy, drug store, or drug department selling prescription drugs shall post a sign at the entrance and where prescription drugs are sold disclosing the fact that upon request**, *before a prescription drug is dispensed,*** a consumer shall be told the price of **[a prescription]** ***such*** drug**, *whether such drug is to be substituted from a list of interchangeable drug products, and of his right to be informed of the price savings resulting from substitution for such drug and to be dispensed the drug as prescribed by the physician, if not satisfied with said price savings*** **[before such prescription drug is dispensed].** Such sign shall not be less than 12 inches by 12 inches.

12. (New section) Any person violating any provision of this act shall be liable to a penalty of not less than $100.00 for the first offense, and not less the $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. ***However, failure of the prescriber to utilize the form of prescription designated in section 8 of this act shall not invalidate the prescription as written, if said prescription is otherwise valid.***

13. (New section) The provisions of sections 5 through 12 shall not be applicable to drug products dispensed under institutional permits when the institution involved has its own drug substitution mechanism.

14. (New section) If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect any other provision or application of the act which can be given effect without such invalid provision or application, and to this end the provisions of this act are declared to be severable.

[14.] ***15.*** (New section) There is hereby appropriated $75,000.00 for the council for the purposes of this act.

[15.] ***16.*** This act shall take effect immediately.

12. (New section) Any person violating any provision of this act shall be liable to a penalty of not less than $100.00 for the first offense, and not less the $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.

13. (New section) The provisions of sections 5 through 12 shall not be applicable to drug products dispensed under institutional permits when the institution involved has its own drug substitution mechanism.

14. (New section) There is hereby appropriated $75,000.00 for the council for the purposes of this act.

15. This act shall take effect immediately.

STATEMENT

This bill addresses the problem of the high cost of many prescription drugs by a two-fold approach. It provides for the dispensing by pharmacists of lower-priced, generic substitutes for prescribed drugs in a strictly regulated manner, and authorizes the advertising of prescription drug prices.

The issue of advertising prescription drug prices, which has generated considerable debate and controversy in recent years, may well be settled now in favor of such advertising as a result of a recent U.S. Supreme Court decision. Our law currently prohibits advertising of prescription drug prices by pharmacists. This bill would eliminate such prohibition and permit advertising in accordance with rules and regulations promulgated by the Director of the Division of Consumer Affairs.

Under current law, doctors may now prescribe drugs generically: This Legislation would extend present law by establishing Drug Utilization Review Council, to compile a drug substitution list subject to appropriate safeguards; it would make available to doctor, pharmacist and consumer, a comparative drug quality and pricing list effectively lowering prices, while maintaining high quality. The doctor has absolute authority to prohibit substitution by checking prescription blank: Do Not Substitute.

The need for this Legislation is urgent, is great. It would give doctors impartial comparative pricing information; it would break

apart restrictive competition among drug companies, which now costs consumers nationally hundreds of millions of dollars; it has been estimated that it would save New Jersey consumers, initially, $7.5 million per year.

We must encourage return of doctor—pharmacist health care partnership. Most doctors do not have time, nor facility, to evaluate all drugs they prescribe; pharmacists now make choice under present law, when doctors prescribe generically; a prestigious Drug Research Board's recent resolution urged that physicians be required to delegate product selection to pharmacist except where doctors explicitly elect to make choice themselves—exactly what this bill provides. The pharmacist's extensive training of drug—drug interaction must be utilized with doctor observation of drug reaction on patient to extend highest quality care at lowest consumer cost.

ASSEMBLY LABOR, INDUSTRY AND PROFESSIONS COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2021

STATE OF NEW JERSEY

DATED: JULY 22, 1976

This bill (1) provides for the dispensing by pharmacists at the option of doctors, dentists and veterinarians of (lower-priced) generic substitutes for prescribed drugs in a manner regulated by the State including the establishment of a Drug Utilization Review Council to supervise the operation of a drug substitution list; (2) authorizes the advertising of prescription drug prices; and (3) provides penalties of from $100.00-$200.00 for violation, with legal action to be taken by the Board of Pharmacy or the Attorney General.

The committee amended the bill to ensure that the advertising of any and all drugs considered hazardous to the public health, safety and welfare by the Commissioner of Health would continue to be prohibited and not just the advertising of those listed in Schedules II through V of the State's Controlled Dangerous Substances Act.

The bill received support from the Department of Health, the Division of Consumer Affairs, the State Medical Society, the North Jersey Federation of Senior Citizens, and the Public Interest Research Group. Its provisions relating to generic drug substitution were opposed by the State AFL-CIO and the pharmaceutical manufacturing industry.

ASSEMBLY COMMITTEE AMENDMENT TO

ASSEMBLY, No. 2021

STATE OF NEW JERSEY

ADOPTED JULY 22, 1976

Amend page 3, section 2, line 93-95, omit "in Schedules II through V of the New Jersey Controlled Dangerous Substances Act, P. L. 1970, c. 226 (C. 24:21-1 et seq.)".

FISCAL NOTE TO

ASSEMBLY, No. 2021

[OFFICIAL COPY REPRINT]

STATE OF NEW JERSEY

DATED: DECEMBER 6, 1976

The Official Copy Reprint of Assembly Bill No. 2021 is designated the "Prescription Drug Price and Quality Stabilization Act". It provides for the dispensing of generic substitutes for prescribed drugs and authorizes the advertising of prescription drug prices.

The Department of Health estimates that enactment of this legislation would require a State expenditure of $129,372.00 in fiscal 1976-77, $125,425.00 in fiscal 1977-78 and $144,699.00 in fiscal 1978-79. The amount estimated for fiscal year 1976-77 would be reduced by an amount dictated by when this legislation is enacted as the estimate is for the complete year.

The fiscal note is based on an estimate of costs rather than actual cost information.

In compliance with written request received, there is hereby submitted a fiscal estimate for the above bill, pursuant to P. L. 1962, c. 27.

SENATE INSTITUTIONS, HEALTH AND WELFARE COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2021

[OFFICIAL COPY REPRINT]

with Senate committee amendment

STATE OF NEW JERSEY

DATED: JUNE 20, 1977

Assembly Bill No. 2021 has two broad purposes: (1) To permit the advertising of prescription drug prices; and (2) To encourage the substitution of cheaper, but therapeutically equivalent, "generic" drugs for more expensive brand name drugs.

The committee considered the bill at length on three separate occasions, hearing a broad range of testimony both in support of, and in opposition to, its provisions. After giving due consideration to the arguments of those opposing Assembly Bill No. 2021, the committee judged them to be without substance and released the bill favorably. The committee made several amendments which improve certain sections of the bill without significantly altering the bill's major provisions.

The first part of Assembly Bill No. 2021 permits the advertising of prescription drug prices by deleting that part of the law which prohibits the promotion of drug prices through the media as "grossly unprofessional conduct," and by authorizing the Director of the Division of Consumer Affairs to promulgate rules governing the advertising of drug prices.

The second part of the bill identifies the conditions under which pharmacists would be permitted to make substitutions for brand name drugs prescribed by physicians.

The bill creates a Drug Utilization Review Council of 11 members, nine to be appointed by the Governor. The Council would prepare a list of interchangeable drug products and periodically revise it. "Interchangeable drug products: are defined as "pharmaceutical equivalents or bioequivalents that are determined to be therapeutic equivalents by the council." Because the definition is so technical the terms which are used in it — "pharmaceutical equivalents," "bioequivalents," and "therapeutic equivalents" — are also defined in the bill. In preparing its list, the Council would have to provide a public hearing on each drug product contemplated for the list, and distribute the list to prescribers and pharmacists throughout the State. Manu-

facturers would be required to submit to the council information related to the manufacturing and testing of their drug products. Before any product is put on the list of interchangeable drug products, its manufacturer would have to demonstrate compliance with the "Good Manufacturing Practices" of Title 21 of the United States Code and, as amended in committee, evidence of satisfactory inspection by the Food and Drug Administration or the New Jersey Department of Health.

As amended by the committee, the bill requires every prescription blank to contain two phrases: "substitution permissible" and "do not substitute." If a physician or other prescriber does *not* initial the "do not substitute" blank or, in the case of an orally transcribed prescription, fails to prohibit a substitution, and if a different, but equivalent, drug is cheaper and appears on the Review Council's list, the pharmacist would be *required* to make a substitution. The committee added language to require that the pharmacist pass on any savings to the consumer in full. The bill also permits a consumer to receive a drug product as originally prescribed by the physician, if the consumer is not satisfied with the price savings that would result from a substitution. (The committee's amendments require pharmacists to tell consumers of the projected price savings.) Another provision of the bill allows the pharmacist to substitute another drug for the prescribed drug, even when the drug to be substituted does not appear on the council's list, *provided* he first obtains the prescriber's approval.

The final sections of the bill: (1) require pharmacies to post signs disclosing that consumers have the right to be told in advance of a drug's price; (2) provide for penalties for violation of the act's provisions; and (3) exempt institutions from the act's substitution provisions when they have their own drug substitution mechanism. In a new section added by the committee, the bill provides that if any part of the act is declared invalid, the remainder of the act nevertheless remains valid and effective.

The bill appropriates $75,000.00 for the expenses of the Drug Utilization Review Council.

This bill was supported in committee by the New Jersey Pharmaceutical Association, the Medical Society of New Jersey, the New Jersey Hospital Association, the New Jersey Education Association, the United Auto Workers, the State Department of Health, the State Division of Consumer Affairs, the State Division of Medical Assistance and Health Services, some local units of the AFL-CIO and several senior citizens' organizations.

Its provisions relating to drug substitution were opposed by the major pharmaceutical manufacturers and the State AFL-CIO.

SENATE, No. 222

STATE OF NEW JERSEY

PRE-FILED FOR INTRODUCTION IN THE 1976 SESSION

By Senator ZANE

AN ACT concerning prescription drugs, authorizing substitutions of drugs under certain circumstances, establishing a Drug Utilization Review Council and prescribing its power and duties, providing for penalties for violations, and making an appropriation.

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

1. As used in this act unless, the context clearly indicates otherwise:

a. "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

b. "Brand name" means the proprietary name assigned to a drug by the manufacturer thereof.

c. "Established name" with respect to a drug or ingredient thereof, means (1) the applicable official name designated pursuant to the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. 301 et seq.), or (2) if there is no such official name and such drug or ingredient is recognized in an official compendium, then the official title thereof in such compendium, except that where a drug or ingredient is recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply, or (3) if neither (1) nor (2) is applicable, then the common or usual name, if any, of such drug or ingredient.

d. "Prescription" means an order for drugs or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease

in man or animals, and includes orders for drugs or medicines or combinations or mixtures thereof transmitted to pharmacists through word of mouth, telephone, telegraph or other means of communication by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

e. "Authorized prescriber" means a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

f. "Council" means the Drug Utilization Review Council.

g. "Chemically equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendial standards.

h. "Reference drug product" means the product which is adopted by the council as the standard for other chemically equivalent drugs in terms of testing for the therapeutic equivalence. In all cases, the reference drug product shall be a currently marketed drug which is the subject of a full, not abbreviated, new drug application approved by the Federal Food and Drug Administration.

i. "Therapeutic equivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy or toxicity.

j. "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

k. "Bioequivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability.

l. "Pharmaceutical equivalents" means those drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage form and that meets standards to be established on the basis of the best available technology.

m. "Interchangeable drug products" means pharmaceutical equivalents or bioequivalents that are determined to be therapeutic equivalents by the council.

n. "Present compendial standards" means the official standards for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia (U.S.P.) and the National Formulary (N.F.).

2. There is hereby established in the Department of Health a Drug Utilization Review Council to consist of eight members appointed by the Governor, and the Commissioner of Health or his designee. Of the members to be appointed by the Governor, two shall be licensed pharmacists, two shall be licensed physicians, two shall be persons with professional scientific or research experience in pharmacology, and two shall be members of the general public. The members appointed by the Governor shall serve for a term of 5 years and until their successors have been appointed and qualified, but of those first appointed, two shall be appointed for a term of 2 years, two for a term of 3 years, two for a term of 4 years, and two for a term of 5 years.

Vacancies shall be filled in the same manner as the original appointments but only for the unexpired term. Council members shall serve without compensation but the members appointed by the Governor shall be entitled to reimbursement for any necessary and reasonable expenses incurred in the performance of their duties hereunder, provided that the amount of such reimbursement shall not exceed $1,000.00 annually.

The council shall meet annually and elect a chairman and secretary from among its members. The chairman and secretary shall serve for a term of 1 year. The council shall meet at such other times to carry out its functions and duties at the call of the chairman or a majority of its members. The council shall be entitled to employ such advisory, technical, and clerical personnel as it deems necessary within the limits of any appropriations made available therefor.

3. a. The council shall prepare a list of interchangeable drug products. This list shall be periodically reviewed in accordance with a schedule of and procedure for such review as shall be established by the council. In development of the list, distinctions shall be made when: (1) evidence of bioequivalence is considered critical and when it is not; (2) when levels of toxicity are considered critical and when they are not. The list may include interchangeable drug products used by the United States Government and its agencies, where the reliability of the drug products interchanged shall have been established.

b. No drug product shall be included in such list until after a public hearing has been held thereon after at least 20 days notice. Such notice shall be mailed to every drug company that is authorized to do business in the State of New Jersey and to all persons who have made a timely request of the council for advance notice

of its public hearings, and shall be published in the New Jersey Register.

c. Manufacturers shall, upon the request of the council, be required to submit any information in their files that relates manufacturing processes and in vivo and in vitro tests to the bioavailability of any drug product. This requirement shall also apply to technical information obtained during research related to the development of new drug products, even when such information bears only an indirect relationship to the final dosage form. The council shall not make such information public when there is a proprietary interest on the part of the manufacturer.

d. Any manufacturer of drug products shall have the right to request the council to evaluate its drug products for the purpose of inclusion on the list of interchangeable drug products, or to request that the council consider removal of any drug product from the list. Any such request shall be accompanied by such information as the council shall require, and any drug product involved shall be evaluated in the same manner and shall be subject to the same procedures and requirements as all other drug products evaluated by the council for inclusion on or removal from the list.

e. The council shall distribute copies of the list of interchangeable drug products and revisions thereof and additions thereto among physicians and other authorized prescribers and licensed pharmacists, and shall supply a copy to any person upon request, upon payment of the price established by the council.

f. The council shall be authorized to adopt reasonable rules and regulations, in accordance with the provisions of the Administrative Procedure Act, P. L. 1968, c. 410 (C. 54:14B–1 et seq.), to carry out its functions and duties under this act and to effectuate its purposes.

4. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the physician's or other authorized prescriber's initials next to the chosen option. Notwithstanding any other law, unless the physician or other authorized prescriber explicitly states that there shall be no substitution when transmitting an oral prescription or, in the case of a written prescription, indicates that there shall be no substitution by initialing the prescription blank next to "do not substitute," a different brand name or non-brand name drug product of the same established name shall be dispensed by a pharmacist if such different brand name or non-brand name drug product shall reflect a lower cost to the consumer

and is contained in the latest list of interchangeable drug products published by the council, provided, however, that such action by the pharmacist shall be authorized only if in each case the pharmacist indicates on the prescription and immediately transmits notice, either orally or by written notice to be mailed no later than the end of the business day, to the prescriber specifying the drug product actually dispensed and the name of the manufacturer thereof. However, no drug interchange shall be made unless a savings to the consumer results, and that savings is passed on to the consumer.

5. Notwithstanding any other law, where a different brand name or nonbrand name drug product of the same established name shall reflect a lower cost to the consumer but is not included in the latest list of interchangeable drug products published by the council, or where in the professional judgment of the pharmacist there is no valid proof of efficacy for the drug product prescribed, or the pharmacist's patient profile record discloses drug sensitivity, allergies or adverse reactions to the drug product prescribed, or there exists a more appropriate drug product than the drug product prescribed, a different brand name or nonbrand name drug product shall be dispensed by the pharmacist, provided, however, that such action by a pharmacist shall be authorized only if in each case the pharmacist notifies the prescriber of the drug product to be dispensed and the name of the manufacturer thereof, and receives the approval of the prescriber to substitute such drug product for the drug product prescribed. The pharmacist shall indicate on the prescription the date and time of the prescriber's approval and whether the approval was communicated orally or in writing.

Whenever the latest list of interchangeable drug products contains drug products of a particular established name, section 4 of this act shall be applicable even though a drug product of the same established name not included on the list would reflect a lower cost to the consumer.

6. If a nonbrand name drug product is dispensed, the pharmacist shall include on the label of any drug product dispensed pursuant to a prescription the brand name of such drug product, or the established name and the name of the manufacturer, except where the prescriber indicates to the contrary on the prescription.

7. Any person violating any provision of this act 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.

8. There is hereby appropriated $75,000.00 for the council for the purposes of this act.

9. This act shall take effect immediately.

ASSEMBLY, No. 2022

STATE OF NEW JERSEY

FROM THE OFFICE OF THE GOVERNOR

9/14/77
G61

SEPTEMBER 29, 1977

FOR IMMEDIATE RELEASE

FOR FURTHER INFORMATION

ANNE BURNS

Governor Brendan Byrne today signed into law the following bills:

A-2021 - sponsored by Assemblyman Martin Herman, D-Gloucester, which is known as the "Prescription Drug Price and Quality Stabilization Act."

The bill amends the Pharmacy Act to allow advertising of prescription drug prices and establishes a Drug Utilization Review Council in the Department of Health to allow substitution of less expensive generic drugs for brand name drugs.

The Council will consist of the Commissioner of Health and the Director of the Division of Consumer Affairs serving as ex officio members and nine members appointed by the Governor for five year terms. These nine appointees will include two licensed pharmacists, two licensed physicians with pharmacological experience, three people with expertise in medical pharmacology and two members of the general public.

The Council will hold public hearings in order to prepare a list of interchangeable drug products. This list will be distributed by the Council among licensed physicians, licensed pharmacist and another person upon request.

Council members will be unsalaried but may receive up to $1000 per year for expenses.

The act will take effect immediately.

S-3149 - sponsored by Senator John J. Fay, D-Middlesex, which creates an Office of the Ombudsman for the Institutionalized Elderly in the Department of Community Affairs.

This office will promote, advocate and insure the adequacy of care received by elderly patients, residents, and clients of facilities within the state.

The office is empowered to investigate complaints as well as initiate actions on its own. Its legal staff will be independent of the Attorney General's Office. The bill provides an appropriation of $150,000 for the initial operation of the new office.

(more)