AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Pharmacy Practice Act of 1987 is amended by changing Section 25 and by adding Section 26 as follows:

(225 ILCS 85/25) (from Ch. 111, par. 4145)

(Section scheduled to be repealed on January 1, 2008)

Sec. 25. No person shall compound, or sell or offer for sale, or cause to be compounded, sold or offered for sale any medicine or preparation under or by a name recognized in the United States Pharmacopoeia National Formulary, for internal or external use, which differs from the standard of strength, quality or purity as determined by the test laid down in the United States Pharmacopoeia National Formulary official at the time of such compounding, sale or offering for sale. Nor shall any person compound, sell or offer for sale, or cause to be compounded, sold, or offered for sale, any drug, medicine, poison, chemical or pharmaceutical preparation, the strength or purity of which shall fall below the professed standard of strength or purity under which it is sold. Except as set forth in Section 26 of this Act, if ~~If~~ the physician or other authorized prescriber, when transmitting an oral or written prescription, does not prohibit drug product selection, a different brand name or nonbrand name drug product of the same generic name may be dispensed by the pharmacist, provided that the selected drug has a unit price less than the drug product specified in the prescription . A generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Illinois Food, Drug and Cosmetic Act, provided that each manufacturer submits to the Director of the Department of Public Health a

notification containing product technical bioequivalence information as a prerequisite to product substitution when they have completed all required testing to support FDA product approval and, in any event, the information shall be submitted no later than 60 days prior to product substitution in the State. On the prescription forms of prescribers, shall be placed a signature line and the words "may substitute" and "may not substitute". The prescriber, in his or her own handwriting, shall place a mark beside either the "may substitute" or "may not substitute" alternatives to guide the pharmacist in the dispensing of the prescription. A prescriber placing a mark beside the "may substitute" alternative or failing in his or her own handwriting to place a mark beside either alternative authorizes drug product selection in accordance with this Act. Preprinted or rubber stamped marks, or other deviations from the above prescription format shall not be permitted. The prescriber shall sign the form in his or her own handwriting to authorize the issuance of the prescription. When a person presents a prescription to be dispensed, the pharmacist to whom it is presented may inform the person if the pharmacy has available a different brand name or nonbrand name of the same generic drug prescribed and the price of the different brand name or nonbrand name of the drug product. If the person presenting the prescription is the one to whom the drug is to be administered, the pharmacist may dispense the prescription with the brand prescribed or a different brand name or nonbrand name product of the same generic name, if the drug is of lesser unit cost and the patient is informed and agrees to the selection and the pharmacist shall enter such information into the pharmacy record. If the person presenting the prescription is someone other than the one to whom the drug is to be administered the pharmacist shall not dispense the prescription with a brand other than the one specified in the prescription unless the pharmacist has the written or oral authorization to select brands from the person to whom the drug is to be administered or a parent, legal guardian or spouse of

that person.

In every case in which a selection is made as permitted by the Illinois Food, Drug and Cosmetic Act, the pharmacist shall indicate on the pharmacy record of the filled prescription the name or other identification of the manufacturer of the drug which has been dispensed.

The selection of any drug product by a pharmacist shall not constitute evidence of negligence if the selected nonlegend drug product was of the same dosage form and each of its active ingredients did not vary by more than 1 percent from the active ingredients of the prescribed, brand name, nonlegend drug product. Failure of a prescribing physician to specify that drug product selection is prohibited does not constitute evidence of negligence unless that practitioner has reasonable cause to believe that the health condition of the patient for whom the physician is prescribing warrants the use of the brand name drug product and not another.

The Department is authorized to employ an analyst or chemist of recognized or approved standing whose duty it shall be to examine into any claimed adulteration, illegal substitution, improper selection, alteration, or other violation hereof, and report the result of his investigation, and if such report justify such action the Department shall cause the offender to be prosecuted.

(Source: P.A. 92-112, eff. 7-20-01; 93-841, eff. 7-30-04.)

(225 ILCS 85/26 new)

(Section scheduled to be repealed on January 1, 2008)

Sec. 26. Anti-epileptic drug product selection prohibited.

(a) The General Assembly finds that this Section is necessary for the immediate preservation of the public peace, health, and safety.

(b) In this Section:

"Anti-epileptic drug means (i) any drug prescribed for the treatment of epilepsy or (ii) a drug used to treat or prevent seizures.

"Epilepsy" means a neurological condition characterized by recurrent seizures.

"Seizure" means a brief disturbance in the electrical activity of the brain.

(c) When the prescribing physician has indicated on the original prescription "dispense as written" or "may not substitute", a pharmacist may not interchange an anti-epileptic drug or formulation of an anti-epileptic drug for the treatment of epilepsy without notification and the documented consent of the prescribing physician and the patient or the patient's parent, legal guardian, or spouse.

Section 10. The Illinois Food, Drug and Cosmetic Act is amended by changing Section 3.14 as follows:

(410 ILCS 620/3.14) (from Ch. 56 1/2, par. 503.14)

Sec. 3.14. Dispensing or causing to be dispensed a different drug in place of the drug or brand of drug ordered or prescribed without the express permission of the person ordering or prescribing. Except as set forth in Section 26 of the Pharmacy Practice Act ~~However~~, this Section does not prohibit the interchange of different brands of the same generically equivalent drug product, when the drug products are not required to bear the legend "Caution: Federal law prohibits dispensing without prescription", provided that the same dosage form is dispensed and there is no greater than 1% variance in the stated amount of each active ingredient of the drug products. A generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration (FDA) shall be available for substitution in Illinois in accordance with this Act and the Pharmacy Practice Act of 1987, provided that each manufacturer submits to the Director of the Department of Public Health a notification containing product technical bioequivalence information as a prerequisite to product substitution when they have completed all required testing to support FDA product approval and, in any event, the

information shall be submitted no later than 60 days prior to product substitution in the State.

(Source: P.A. 92-112, eff. 7-20-01; 93-841, eff. 7-30-04.)

Section 99. Effective date. This Act takes effect upon becoming law.