Sen. Dan Kotowski

Filed: 3/25/2009

AMENDMENT TO SENATE BILL 2060

AMENDMENT NO. _____. Amend Senate Bill 2060 by replacing everything after the enacting clause with the following:

"Section 5. The Pharmacy Practice Act is amended by changing Section 25 as follows:

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

(Section scheduled to be repealed on January 1, 2018)

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 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 not substitute". The prescriber, in his or her own handwriting, shall place a mark beside "may not substitute" to direct the pharmacist in the dispensing of the prescription. 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 generic substitution is authorized under this Section, the pharmacist shall inform the prescriber and the patient; the patient shall have the option to elect either the generic or prescribed drug.

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.

A person convicted of violating this Section shall be fined not less than $2,000 for the first violation, not less than $5,000 for the second violation, and not less than $10,000 for any third or subsequent violation. Each prescription dispensed in violation of this Section shall be a separate violation.

(Source: P.A. 94-936, eff. 6-26-06; 95-689, eff. 10-29-07.)".