

1 AN ACT concerning regulation.

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

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

6 (225 ILCS 85/25) (from Ch. 111, par. 4145)

7 (Section scheduled to be repealed on January 1, 2008)

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

1 notification containing product technical bioequivalence  
2 information as a prerequisite to product substitution when they  
3 have completed all required testing to support FDA product  
4 approval and, in any event, the information shall be submitted  
5 no later than 60 days prior to product substitution in the  
6 State. On the prescription forms of prescribers, shall be  
7 placed a signature line and the words "may substitute" and "may  
8 not substitute". The prescriber, in his or her own handwriting,  
9 shall place a mark beside either the "may substitute" or "may  
10 not substitute" alternatives to guide the pharmacist in the  
11 dispensing of the prescription. A prescriber placing a mark  
12 beside the "may substitute" alternative or failing in his or  
13 her own handwriting to place a mark beside either alternative  
14 authorizes drug product selection in accordance with this Act.  
15 Preprinted or rubber stamped marks, or other deviations from  
16 the above prescription format shall not be permitted. The  
17 prescriber shall sign the form in his or her own handwriting to  
18 authorize the issuance of the prescription. When a person  
19 presents a prescription to be dispensed, the pharmacist to whom  
20 it is presented may inform the person if the pharmacy has  
21 available a different brand name or nonbrand name of the same  
22 generic drug prescribed and the price of the different brand  
23 name or nonbrand name of the drug product. If the person  
24 presenting the prescription is the one to whom the drug is to  
25 be administered, the pharmacist may dispense the prescription  
26 with the brand prescribed or a different brand name or nonbrand  
27 name product of the same generic name, if the drug is of lesser  
28 unit cost and the patient is informed and agrees to the  
29 selection and the pharmacist shall enter such information into  
30 the pharmacy record. If the person presenting the prescription  
31 is someone other than the one to whom the drug is to be  
32 administered the pharmacist shall not dispense the  
33 prescription with a brand other than the one specified in the  
34 prescription unless the pharmacist has the written or oral  
35 authorization to select brands from the person to whom the drug  
36 is to be administered or a parent, legal guardian or spouse of

1 that person.

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

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

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

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

26 (225 ILCS 85/26 new)

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

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

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

32 (b) In this Section:

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

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

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

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

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

14       (410 ILCS 620/3.14) (from Ch. 56 1/2, par. 503.14)

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

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

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

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