

SB2578



94TH GENERAL ASSEMBLY
State of Illinois
2005 and 2006
SB2578

Introduced 1/20/2006, by Sen. Carol Ronen

SYNOPSIS AS INTRODUCED:

225 ILCS 85/25
225 ILCS 85/26 new

from Ch. 111, par. 4145

Amends the Pharmacy Practice Act of 1987. Prohibits drug product selection in refills of anti-epileptic drugs without notification and the documented consent of the prescriber and patient or the participating provider. Effective immediately.

LRB094 17772 RAS 53071 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

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7 (Section scheduled to be repealed on January 1, 2008)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

30 "Anti-epileptic drug means (i) any drug prescribed for the
31 treatment of epilepsy or (ii) a drug used to treat or prevent
32 convulsions that may pose a health risk to a patient if
33 interchanged with another pharmaceutical manufacturer's
34 product.

35 "Epilepsy" means a disorder of brain function that may or

1 may not be associated with damage to brain structures.

2 "Refill" means a new prescription written at the expiration
3 of the then current issued prescription that continues the
4 patient's therapy on a particular epilepsy drug.

5 (b) Drug product selection, as authorized under Section 25
6 of this Act, shall not apply to the refill of a prescription
7 for any anti-epileptic drug intended for the treatment of
8 epilepsy.

9 (c) A pharmacist may not interchange an equivalent
10 anti-epileptic drug for the treatment of epilepsy without
11 notification and the documented consent of the prescriber and
12 patient.

13 (d) A participating provider shall determine the
14 appropriate anti-epileptic drug therapy for an enrollee. A
15 prescription for any anti-epileptic drug shall be refilled
16 using the same drug product by the same manufacturer, whether
17 brand name or generic, that the pharmacist last dispensed under
18 that prescription, unless, prior to the dispensing of another
19 pharmaceutical manufacturer's product, the pharmacist so
20 notifies the participating provider and the participating
21 provider gives documented consent thereto. A carrier shall not
22 penalize the participating provider, the dispensing
23 pharmacist, or the enrollee, financially or otherwise, for
24 prescribing, dispensing, or requesting a specific drug for the
25 treatment of epilepsy.

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