



97TH GENERAL ASSEMBLY

State of Illinois

2011 and 2012

HB0254

Introduced 01/25/11, by Rep. Rosemary Mulligan

SYNOPSIS AS INTRODUCED:

225 ILCS 85/25

from Ch. 111, par. 4145

Amends the Pharmacy Practice Act. In a provision concerning dispensing prescriptions, provides that if the physician or other authorized prescriber prescribes a drug and the pharmacy dispenses a generic, then the pharmacist must notify the patient or customer when he or she is dispensing a generic drug with the same active pharmaceutical ingredient by a different manufacturer than most recently previously dispensed for the patient by that pharmacy. Effective immediately.

LRB097 03038 CEL 43069 b

1 AN ACT concerning professional 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 is amended by changing
5 Section 25 as follows:

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

7 (Section scheduled to be repealed on January 1, 2018)

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 the physician or other authorized
22 prescriber, when transmitting an oral or written prescription,
23 does not prohibit drug product selection, a different brand

1 name or nonbrand name drug product of the same generic name may
2 be dispensed by the pharmacist, provided that the selected drug
3 has a unit price less than the drug product specified in the
4 prescription. A generic drug determined to be therapeutically
5 equivalent by the United States Food and Drug Administration
6 (FDA) shall be available for substitution in Illinois in
7 accordance with this Act and the Illinois Food, Drug and
8 Cosmetic Act, provided that each manufacturer submits to the
9 Director of the Department of Public Health a notification
10 containing product technical bioequivalence information as a
11 prerequisite to product substitution when they have completed
12 all required testing to support FDA product approval and, in
13 any event, the information shall be submitted no later than 60
14 days prior to product substitution in the State. On the
15 prescription forms of prescribers, shall be placed a signature
16 line and the words "may not substitute". The prescriber, in his
17 or her own handwriting, shall place a mark beside "may not
18 substitute" to direct the pharmacist in the dispensing of the
19 prescription. Preprinted or rubber stamped marks, or other
20 deviations from the above prescription format shall not be
21 permitted. The prescriber shall sign the form in his or her own
22 handwriting to authorize the issuance of the prescription.

23 If a physician or other authorized prescriber prescribes a
24 drug and the pharmacy dispenses a generic, then it shall be the
25 policy of every pharmacy operating in this State to require the
26 pharmacist to notify the patient, patient's designee, or

1 customer when he or she is dispensing a generic drug with the
2 same active pharmaceutical ingredient by a different
3 manufacturer than most recently previously dispensed for the
4 patient by that pharmacy. This amendatory Act of the 97th
5 General Assembly shall not be construed to affect the
6 dispensing of drugs when the prescriber has marked "may not
7 substitute" on the prescription form.

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

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

24 The Department is authorized to employ an analyst or
25 chemist of recognized or approved standing whose duty it shall
26 be to examine into any claimed adulteration, illegal

1 substitution, improper selection, alteration, or other
2 violation hereof, and report the result of his investigation,
3 and if such report justify such action the Department shall
4 cause the offender to be prosecuted.

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

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