



93RD GENERAL ASSEMBLY
State of Illinois
2003 and 2004

Introduced 2/4/2004, by Barack Obama

SYNOPSIS AS INTRODUCED:

225 ILCS 85/3	from Ch. 111, par. 4123
225 ILCS 85/16a	from Ch. 111, par. 4136a

Amends the Pharmacy Practice Act of 1987. Changes the definition of "mail-order pharmacy" and the provisions concerning registration of mail-order pharmacies to include pharmacies located outside of Illinois (rather than in a state of the United States). Allows the Department to make site visits to a mail-order pharmacy and notify the United States Food and Drug Administration that a mail-order pharmacy registered under the provisions is in compliance with State laws and rules governing mail-order pharmacies.

LRB093 20854 AMC 46788 b

FISCAL NOTE ACT
MAY APPLY

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 of 1987 is amended by
5 changing Sections 3 and 16a as follows:

6 (225 ILCS 85/3) (from Ch. 111, par. 4123)

7 (Section scheduled to be repealed on January 1, 2008)

8 Sec. 3. Definitions. For the purpose of this Act, except
9 where otherwise limited therein:

10 (a) "Pharmacy" or "drugstore" means and includes every
11 store, shop, pharmacy department, or other place where
12 pharmaceutical care is provided by a pharmacist (1) where
13 drugs, medicines, or poisons are dispensed, sold or offered for
14 sale at retail, or displayed for sale at retail; or (2) where
15 prescriptions of physicians, dentists, veterinarians,
16 podiatrists, or therapeutically certified optometrists, within
17 the limits of their licenses, are compounded, filled, or
18 dispensed; or (3) which has upon it or displayed within it, or
19 affixed to or used in connection with it, a sign bearing the
20 word or words "Pharmacist", "Druggist", "Pharmacy",
21 "Pharmaceutical Care", "Apothecary", "Drugstore", "Medicine
22 Store", "Prescriptions", "Drugs", "Medicines", or any word or
23 words of similar or like import, either in the English language
24 or any other language; or (4) where the characteristic
25 prescription sign (Rx) or similar design is exhibited; or (5)
26 any store, or shop, or other place with respect to which any of
27 the above words, objects, signs or designs are used in any
28 advertisement.

29 (b) "Drugs" means and includes (1) articles recognized in
30 the official United States Pharmacopoeia/National Formulary
31 (USP/NF), or any supplement thereto and being intended for and
32 having for their main use the diagnosis, cure, mitigation,

1 treatment or prevention of disease in man or other animals, as
2 approved by the United States Food and Drug Administration, but
3 does not include devices or their components, parts, or
4 accessories; and (2) all other articles intended for and having
5 for their main use the diagnosis, cure, mitigation, treatment
6 or prevention of disease in man or other animals, as approved
7 by the United States Food and Drug Administration, but does not
8 include devices or their components, parts, or accessories; and
9 (3) articles (other than food) having for their main use and
10 intended to affect the structure or any function of the body of
11 man or other animals; and (4) articles having for their main
12 use and intended for use as a component or any articles
13 specified in clause (1), (2) or (3); but does not include
14 devices or their components, parts or accessories.

15 (c) "Medicines" means and includes all drugs intended for
16 human or veterinary use approved by the United States Food and
17 Drug Administration.

18 (d) "Practice of pharmacy" means the provision of
19 pharmaceutical care to patients as determined by the
20 pharmacist's professional judgment in the following areas,
21 which may include but are not limited to (1) patient
22 counseling, (2) interpretation and assisting in the monitoring
23 of appropriate drug use and prospective drug utilization
24 review, (3) providing information on the therapeutic values,
25 reactions, drug interactions, side effects, uses, selection of
26 medications and medical devices, and outcome of drug therapy,
27 (4) participation in drug selection, drug monitoring, drug
28 utilization review, evaluation, administration,
29 interpretation, application of pharmacokinetic and laboratory
30 data to design safe and effective drug regimens, (5) drug
31 research (clinical and scientific), and (6) compounding and
32 dispensing of drugs and medical devices.

33 (e) "Prescription" means and includes any written, oral,
34 facsimile, or electronically transmitted order for drugs or
35 medical devices, issued by a physician licensed to practice
36 medicine in all its branches, dentist, veterinarian, or

1 podiatrist, or therapeutically certified optometrist, within
2 the limits of their licenses, by a physician assistant in
3 accordance with subsection (f) of Section 4, or by an advanced
4 practice nurse in accordance with subsection (g) of Section 4,
5 containing the following: (1) name of the patient; (2) date
6 when prescription was issued; (3) name and strength of drug or
7 description of the medical device prescribed; and (4) quantity,
8 (5) directions for use, (6) prescriber's name, address and
9 signature, and (7) DEA number where required, for controlled
10 substances. DEA numbers shall not be required on inpatient drug
11 orders.

12 (f) "Person" means and includes a natural person,
13 copartnership, association, corporation, government entity, or
14 any other legal entity.

15 (g) "Department" means the Department of Professional
16 Regulation.

17 (h) "Board of Pharmacy" or "Board" means the State Board of
18 Pharmacy of the Department of Professional Regulation.

19 (i) "Director" means the Director of Professional
20 Regulation.

21 (j) "Drug product selection" means the interchange for a
22 prescribed pharmaceutical product in accordance with Section
23 25 of this Act and Section 3.14 of the Illinois Food, Drug and
24 Cosmetic Act.

25 (k) "Inpatient drug order" means an order issued by an
26 authorized prescriber for a resident or patient of a facility
27 licensed under the Nursing Home Care Act or the Hospital
28 Licensing Act, or "An Act in relation to the founding and
29 operation of the University of Illinois Hospital and the
30 conduct of University of Illinois health care programs",
31 approved July 3, 1931, as amended, or a facility which is
32 operated by the Department of Human Services (as successor to
33 the Department of Mental Health and Developmental
34 Disabilities) or the Department of Corrections.

35 (k-5) "Pharmacist" means an individual health care
36 professional and provider currently licensed by this State to

1 engage in the practice of pharmacy.

2 (l) "Pharmacist in charge" means the licensed pharmacist
3 whose name appears on a pharmacy license and who is responsible
4 for all aspects of the operation related to the practice of
5 pharmacy.

6 (m) "Dispense" means the delivery of drugs and medical
7 devices, in accordance with applicable State and federal laws
8 and regulations, to the patient or the patient's representative
9 authorized to receive these products, including the
10 compounding, packaging, and labeling necessary for delivery,
11 and any recommending or advising concerning the contents and
12 therapeutic values and uses thereof. "Dispense" does not mean
13 the physical delivery to a patient or a patient's
14 representative in a home or institution by a designee of a
15 pharmacist or by common carrier. "Dispense" also does not mean
16 the physical delivery of a drug or medical device to a patient
17 or patient's representative by a pharmacist's designee within a
18 pharmacy or drugstore while the pharmacist is on duty and the
19 pharmacy is open.

20 (n) "Mail-order pharmacy" means a pharmacy that is located
21 outside of Illinois ~~in a state of the United States, other than~~
22 ~~Illinois,~~ that delivers, dispenses or distributes, through the
23 United States Postal Service or other common carrier, to
24 Illinois residents, any substance which requires a
25 prescription.

26 (o) "Compounding" means the preparation, mixing,
27 assembling, packaging, or labeling of a drug or medical device:
28 (1) as the result of a practitioner's prescription drug order
29 or initiative that is dispensed pursuant to a prescription in
30 the course of professional practice; or (2) for the purpose of,
31 or incident to, research, teaching, or chemical analysis; or
32 (3) in anticipation of prescription drug orders based on
33 routine, regularly observed prescribing patterns.

34 (p) "Confidential information" means information,
35 maintained by the pharmacist in the patient's records, released
36 only (i) to the patient or, as the patient directs, to other

1 practitioners and other pharmacists or (ii) to any other person
2 authorized by law to receive the information.

3 (q) "Prospective drug review" or "drug utilization
4 evaluation" means a screening for potential drug therapy
5 problems due to therapeutic duplication, drug-disease
6 contraindications, drug-drug interactions (including serious
7 interactions with nonprescription or over-the-counter drugs),
8 drug-food interactions, incorrect drug dosage or duration of
9 drug treatment, drug-allergy interactions, and clinical abuse
10 or misuse.

11 (r) "Patient counseling" means the communication between a
12 pharmacist or a student pharmacist under the direct supervision
13 of a pharmacist and a patient or the patient's representative
14 about the patient's medication or device for the purpose of
15 optimizing proper use of prescription medications or devices.
16 The offer to counsel by the pharmacist or the pharmacist's
17 designee, and subsequent patient counseling by the pharmacist
18 or student pharmacist, shall be made in a face-to-face
19 communication with the patient or patient's representative
20 unless, in the professional judgment of the pharmacist, a
21 face-to-face communication is deemed inappropriate or
22 unnecessary. In that instance, the offer to counsel or patient
23 counseling may be made in a written communication, by
24 telephone, or in a manner determined by the pharmacist to be
25 appropriate.

26 (s) "Patient profiles" or "patient drug therapy record"
27 means the obtaining, recording, and maintenance of patient
28 prescription information, including prescriptions for
29 controlled substances, and personal information.

30 (t) "Pharmaceutical care" includes, but is not limited to,
31 the act of monitoring drug use and other patient care services
32 intended to achieve outcomes that improve the patient's quality
33 of life but shall not include the sale of over-the-counter
34 drugs by a seller of goods and services who does not dispense
35 prescription drugs.

36 (u) "Medical device" means an instrument, apparatus,

1 implement, machine, contrivance, implant, in vitro reagent, or
2 other similar or related article, including any component part
3 or accessory, required under federal law to bear the label
4 "Caution: Federal law requires dispensing by or on the order of
5 a physician". A seller of goods and services who, only for the
6 purpose of retail sales, compounds, sells, rents, or leases
7 medical devices shall not, by reasons thereof, be required to
8 be a licensed pharmacy.

9 (v) "Unique identifier" means an electronic signature,
10 handwritten signature or initials, thumb print, or other
11 acceptable individual biometric or electronic identification
12 process as approved by the Department.

13 (Source: P.A. 92-880, eff. 1-1-04; 93-571, eff. 8-20-03.)

14 (225 ILCS 85/16a) (from Ch. 111, par. 4136a)

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

16 Sec. 16a. Mail-order pharmacies.

17 (a) The Department shall establish rules and regulations,
18 consistent with the provisions of this Act, governing
19 mail-order pharmacies, including pharmacies providing services
20 via the Internet, which sell, or offer for sale, drugs,
21 medicines, or other pharmaceutical services in this State.

22 (b) The Board shall require and provide for an annual
23 nonresident special pharmacy registration for all pharmacies
24 located outside of this State that dispense medications for
25 Illinois residents and mail, ship, or deliver prescription
26 medications into this State. Nonresident special pharmacy
27 registration shall be granted by the Board upon the disclosure
28 and certification by a pharmacy:

29 (1) that it is licensed in the jurisdiction ~~state~~ in
30 which the dispensing facility is located and from which the
31 drugs are dispensed;

32 (2) of the location, names, and titles of all principal
33 corporate officers and all pharmacists who are dispensing
34 drugs to residents of this State;

35 (3) that it complies with all lawful directions and

1 requests for information from the board of pharmacy of each
2 state in which it is licensed or registered, except that it
3 shall respond directly to all communications from the Board
4 concerning emergency circumstances arising from the
5 dispensing of drugs to residents of this State;

6 (4) that it maintains its records of drugs dispensed to
7 residents of this State so that the records are readily
8 retrievable from the records of other drugs dispensed;

9 (5) that it cooperates with the Board in providing
10 information to the board of pharmacy of the jurisdiction
11 ~~state~~ in which it is licensed concerning matters related to
12 the dispensing of drugs to residents of this State; and

13 (6) that during its regular hours of operation, but not
14 less than 6 days per week, for a minimum of 40 hours per
15 week, a toll-free telephone service is provided to
16 facilitate communication between patients in this State
17 and a pharmacist at the pharmacy who has access to the
18 patients' records. The toll-free number must be disclosed
19 on the label affixed to each container of drugs dispensed
20 to residents of this State.

21 (c) The Department may (i) in cooperation with the
22 jurisdiction under which the pharmacy is licensed, make site
23 visits to a pharmacy registered under this Section for quality
24 assurance purposes and (ii) notify the United States Food and
25 Drug Administration that a pharmacy registered under this
26 Section is in compliance with State laws and rules governing
27 mail-order pharmacies.

28 (Source: P.A. 91-438, eff. 1-1-00.)