HB0647

LRB094 04105 RAS 34125 b

94TH GENERAL ASSEMBLY

State of Illinois

2005 and 2006

HB0647

Introduced 1/28/2005, by Rep. Jack D. Franks

SYNOPSIS AS INTRODUCED:

225 ILCS 85/3	from Ch. 111, par. 4123
225 ILCS 85/16a	from Ch. 111, par. 4136a
225 ILCS 85/16b new	
225 ILCS 85/35.1	from Ch. 111, par. 4155.1

Amends the Pharmacy Practice Act of 1987. Provides for the registration of foreign mail-order pharmacies as nonresident pharmacies if specified disclosures and certifications are provided and the pharmacies are located in a foreign country, state or province whose pharmacy laws and regulations have been determined by the Department of Financial and Professional Regulation to be substantially similar to those of the State of Illinois and whose regulatory scheme for approval and quality contro of prescription drugs has been found by the Department to be substantially equivalent tol that of the State of Illinois and the federal government. Effective immediately.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning pharmacies.

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

Section 5. The Pharmacy Practice Act of 1987 is amended by changing Sections 3, 16a, and 35.1 and adding Section 16b as follows:

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

(Section scheduled to be repealed on January 1, 2008)

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

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

(b) "Drugs" means and includes (l) articles recognized in the official United States Pharmacopoeia/National Formulary (USP/NF), or any supplement thereto and being intended for and

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

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

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

(e) "Prescription" means and includes any written, oral, facsimile, or electronically transmitted order for drugs or medical devices, issued by a physician licensed to practice

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

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

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

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

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

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

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

(k-5) "Pharmacist" means an individual health care

professional and provider currently licensed by this State to engage in the practice of pharmacy.

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

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

(n) "Domestic mail-order pharmacy" means a pharmacy that is located in a state of the United States, other than Illinois, that delivers, dispenses or distributes, through the United States Postal Service or other common carrier, to Illinois residents, any substance which requires a prescription.

(n-5) "Foreign mail-order pharmacy" means a pharmacy that is located in a country other than the United States that delivers, dispenses, or distributes, through the United States Postal Service or other common carrier, to Illinois residents any substance that requires a prescription.

(o) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or medical device: (1) as the result of a practitioner's prescription drug order or initiative that is dispensed pursuant to a prescription in the course of professional practice; or (2) for the purpose of, or incident to, research, teaching, or chemical analysis; or

(3) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(p) "Confidential information" means information, maintained by the pharmacist in the patient's records, released only (i) to the patient or, as the patient directs, to other practitioners and other pharmacists or (ii) to any other person authorized by law to receive the information.

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

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

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

(t) "Pharmaceutical care" includes, but is not limited to, the act of monitoring drug use and other patient care services

intended to achieve outcomes that improve the patient's quality of life but shall not include the sale of over-the-counter drugs by a seller of goods and services who does not dispense prescription drugs.

(u) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, required under federal law to bear the label "Caution: Federal law requires dispensing by or on the order of a physician". A seller of goods and services who, only for the purpose of retail sales, compounds, sells, rents, or leases medical devices shall not, by reasons thereof, be required to be a licensed pharmacy.

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

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

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

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

Sec. 16a. (a) The Department shall establish rules and regulations, consistent with the provisions of this Act, governing <u>domestic</u> mail-order pharmacies, including pharmacies providing services via the Internet, which sell, or offer for sale, drugs, medicines, or other pharmaceutical services in this State.

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

(1) that it is licensed in the state in which the dispensing facility is located and from which the drugs are

dispensed;

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

(3) that it complies with all lawful directions and requests for information from the board of pharmacy of each state in which it is licensed or registered, except that it shall respond directly to all communications from the Board concerning emergency circumstances arising from the dispensing of drugs to residents of this State;

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

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

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

(c) The provisions of this Section do not apply to pharmacies for which registration is provided under Section 16b.

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

(225 ILCS 85/16b new)

Sec. 16b. Foreign mail-order pharmacy.

(a) Notwithstanding any other Section of this Act, the Department shall provide for the registration of foreign mail-order pharmacies as nonresident pharmacies, upon the disclosure and certification by a foreign mail-order pharmacy

of the following:

(1) That it is licensed in the country, state, or province in which the dispensing facility is located and from which the drugs are dispensed.

(2) The location, names, and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this State.

(3) That it complies with all lawful directions and requests for information from the board of pharmacy of each country, state, or province in which it is licensed or registered, except that it shall respond directly to all communications from the Board concerning emergency circumstances arising from the dispensing of drugs to residents of this State.

(4) That it maintains its records of drugs dispensed to residents of this State so that the records are readily retrievable from the records of other drugs dispensed.

(5) That it cooperates with the Board of Pharmacy in providing information to the board of pharmacy of the country, state, or province in which it is licensed concerning matters related to the dispensing of drugs to residents of this State.

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

(7) That it consents to the jurisdiction of the Department over pharmacy practices affecting the State of Illinois.

(b) Only a pharmacy located within a foreign country, state, or province whose pharmacy laws and regulations have been determined by the Department to be substantially similar

to those of the State of Illinois and whose regulatory scheme for approval and quality control of prescription drugs has been found by the Department to be substantially equivalent to that of the State of Illinois and the federal government may be registered as a nonresident pharmacy.

(c) The Department's criteria for determining substantial equivalence shall be set by rule.

(d) The Department shall maintain a list of all foreign countries, states, and provinces that have been evaluated on its website with a designation of "approved" or "denied". Any pharmacy located within a foreign country, state, or province that has not been evaluated by the Department may request that the Department conduct an evaluation.

(225 ILCS 85/35.1) (from Ch. 111, par. 4155.1)

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

Sec. 35.1. (a) If any person violates the provision of this Act, the Director may, in the name of the People of the State of Illinois, through the Attorney General of the State of Illinois, or the State's Attorney of any county in which the action is brought, petition, for an order enjoining such violation or for an order enforcing compliance with this Act. Upon the filing of a verified petition in such court, the court may issue a temporary restraining order, without notice or bond, and may preliminarily and permanently enjoin such violation, and if it is established that such person has violated or is violating the injunction, the Court may punish the offender for contempt of court. Proceedings under this Section shall be in addition to, and not in lieu of, all other remedies and penalties provided by this Act.

(b) If any person shall practice as a pharmacist or hold himself out as a pharmacist or operate a pharmacy or drugstore, including a domestic mail-order pharmacy under Section 16a or a foreign mail-order pharmacy under Section 16b, without being licensed under the provisions of this Act, then any licensed pharmacist, any interested party or any person injured thereby

may, in addition to the Director, petition for relief as provided in subsection (a) of this Section.

Whoever knowingly practices or offers to practice in this State without being appropriately licensed or registered under this Act shall be guilty of a Class A misdemeanor and for each subsequent conviction, shall be guilty of a Class 4 felony.

(c) Whenever in the opinion of the Department any person not licensed in good standing under this Act violates any provision of this Act, the Department may issue a rule to show cause why an order to cease and desist should not be entered against him. The rule shall clearly set forth the grounds relied upon by the Department and shall provide a period of 7 days from the date of the rule to file an answer to the satisfaction of the Department. Failure to answer to the satisfaction of the Department shall cause an order to cease and desist to be issued forthwith.

(Source: P.A. 92-678, eff. 7-16-02.)

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