Rep. Angelo Saviano

Filed: 4/5/2005

AMENDMENT TO HOUSE BILL 1031

AMENDMENT NO. _____. Amend House Bill 1031 by replacing everything after the enacting clause with the following:

"Section 5. The Pharmacy Practice Act of 1987 is amended by changing Sections 3, 14, 15, and 18 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(Section scheduled to be repealed on January 1, 2008)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 (l), (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. A pharmacist may provide pharmaceutical care in conjunction with or independent of a licensed 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 preparation, compounding, packaging, and labeling necessary for delivery, computer entry, and verification of medication orders and prescriptions, 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) "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.

(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; 93-1075, eff. 1-18-05.)

(225 ILCS 85/14) (from Ch. 111, par. 4134)

(Section scheduled to be repealed on January 1, 2008)

Sec. 14. Structural and equipment requirements. No person shall establish or move to a new location any pharmacy unless the pharmacy is licensed with the Department and has on file with the Department a verified statement that:

(1) such pharmacy is or will be engaged in the practice of pharmacy; and

(2) <u>other than a Division VI pharmacy,</u> such pharmacy will have in stock and shall maintain sufficient drugs and materials as to protect the public it serves within 30 days after the issuance of the registration of the pharmacy.

Division I, II, III, IV, or V pharmacies shall be in a suitable, well-lighted and well-ventilated area with at least 300 square feet of clean and sanitary contiguous space and shall be suitably equipped for compounding prescriptions, storage of drugs and sale of drugs and to otherwise conduct the practice of pharmacy. The space occupied shall be equipped with a sink with hot and cold water or facilities for heating water, proper sewage outlet, refrigeration storage equipment, and such fixtures, facilities, drugs, equipment and material, which shall include the current editions of the United States Pharmacopoeia/DI, Facts and Comparisons, or any other current compendium approved by the Department, and other such reference works, as will enable a pharmacist to practice pharmacy, including this Act and the rules promulgated under this Act. Such pharmacy shall have the following items: accurate weights of 0.5 gr. to 4 oz. and 20 mg to 100 Gm; and a prescription balance equipped with balance indicator and with mechanical means of arresting the oscillations of the mechanism and which balance shall be sensitive to 0.5 grain (32 mg) or less or an alternative weighing device as approved by the Department, and such other measuring devices as may be necessary for the conduct of the practice of pharmacy.

The provisions of this Section with regard to 300 square

feet of space shall apply to any pharmacy which is opened after the effective date of this Act. Nothing shall require a pharmacy in existence on the effective date of this Act which is comprised of less than 300 square feet to provide additional space to meet these requirements.

Any structural and equipment requirements for a Division VI pharmacy shall be set by rule.

(Source: P.A. 92-880, eff. 1-1-04.)

(225 ILCS 85/15) (from Ch. 111, par. 4135)

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

Sec. 15. Pharmacy requirements. It shall be unlawful for the owner of any pharmacy, as defined in this Act, to operate or conduct the same, or to allow the same to be operated or conducted, unless:

(a) It has a licensed pharmacist, authorized to practice pharmacy in this State under the provisions of this Act, on duty whenever the practice of pharmacy is conducted;

(b) Security provisions for all drugs and devices, as determined by rule of the Department, are provided during the absence from the licensed pharmacy of all licensed pharmacists. Maintenance of security provisions is the responsibility of the licensed registered pharmacist in charge; and

(c) The pharmacy is licensed under this Act to do business.

The Department shall, by rule, provide requirements for each division of pharmacy license and shall, as well provide guidelines for the designation of a registered pharmacist in charge for each division.

Division I. Retail Licenses for pharmacies which are open to, or offer pharmacy services to, the general public.

Division II. Licenses for pharmacies whose primary pharmacy service is provided to patients or residents of facilities 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, and which are not located in the facilities they serve.

Division III. Licenses for pharmacies which are located in 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, and which provide pharmacy services to residents or patients of the facility, as well as employees, prescribers and students of the facility.

Division IV. Licenses for pharmacies which provide or offer for sale radioactive materials.

Division V. Licenses for pharmacies which hold licenses in Division II or Division III which also provide pharmacy services to the general public, or pharmacies which are located in or whose primary pharmacy service is to ambulatory care facilities or schools of veterinary medicine or other such institution or facility.

Division VI. Licenses for pharmacies that provide pharmacy services to patients of institutions serviced by pharmacies with a Division II or Division III license, without using their own supply of drugs. Division VI pharmacies may provide pharmacy services only in cooperation with an institution's pharmacy or pharmacy provider. Nothing in this paragraph shall constitute a change to the practice of pharmacy as defined in Section 3 of this Act. Nothing in this amendatory Act of the 94th General Assembly shall in any way alter the definition or operation of any other division of pharmacy as provided in this

Act.

The Director may waive the requirement for a pharmacist to be on duty at all times for State facilities not treating human ailments.

It shall be unlawful for any person, who is not a licensed pharmacy or health care facility, to purport to be such or to use in name, title, or sign designating, or in connection with that place of business, any of the words: "pharmacy", "pharmacist", "pharmacy department", "apothecary", "druggist", "drug", "drugs", "medicines", "medicine store", "drug sundries", "prescriptions filled", or any list of words indicating that drugs are compounded or sold to the lay public, or prescriptions are dispensed therein. Each day during which, or a part which, such representation is made or appears or such a sign is allowed to remain upon or in such a place of business shall constitute a separate offense under this Act.

The holder of any license or certificate of registration shall conspicuously display it in the pharmacy in which he is engaged in the practice of pharmacy. The registered pharmacist in charge shall conspicuously display his name in such pharmacy. The pharmacy license shall also be conspicuously displayed.

(Source: P.A. 92-880, eff. 1-1-04.)

(225 ILCS 85/18) (from Ch. 111, par. 4138)

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

Sec. 18. Record retention.

(a) Except as provided in subsection (b), there ~~There~~ shall be kept in every drugstore or pharmacy a suitable book, file, or electronic record keeping system in which shall be preserved for a period of not less than 5 years the original of every written prescription and the original transcript or copy of every verbal prescription filled, compounded, or dispensed, in such pharmacy; and such book or file of prescriptions shall at

all reasonable times be open to inspection to the pharmacy coordinator and the duly authorized agents or employees of the Department.

Every prescription filled or refilled shall contain the unique identifier of the person authorized to practice pharmacy under the provision of this Act who fills or refills the prescription.

Records kept pursuant to this Section may be maintained in an alternative data retention system, such as a direct digital imaging system, provided that:

(1) the records maintained in the alternative data retention system contain all of the information required in a manual record;

(2) the data processing system is capable of producing a hard copy of the electronic record on the request of the Board, its representative, or other authorized local, State, or federal law enforcement or regulatory agency; and

(3) the digital images are recorded and stored only by means of a technology that does not allow subsequent revision or replacement of the images.

As used in this Section, "digital imaging system" means a system, including people, machines, methods of organization, and procedures, that provides input, storage, processing, communications, output, and control functions for digitized representations of original prescription records.

Inpatient drug orders may be maintained within an institution in a manner approved by the Department.

(b) The record retention requirements for a Division VI pharmacy shall be set by rule.

(Source: P.A. 92-880, eff. 1-1-04.)

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