

94TH GENERAL ASSEMBLY State of Illinois 2005 and 2006 HB2574

Introduced 02/18/05, by Rep. Angelo Saviano

SYNOPSIS AS INTRODUCED:

22	5 ILCS	85/14	${\tt from}$	Ch.	111,	par.	4134
22	5 ILCS	85/15	from	Ch.	111,	par.	4135
22	5 ILCS	85/18	${\tt from}$	Ch.	111,	par.	4138
22	5 ILCS	85/30	from	Ch.	111,	par.	4150

Amends the Pharmacy Practice Act of 1987. Adds a Division VI license for pharmacies located in Illinois and providing pharmaceutical care to patients of institutions maintaining a Division III pharmacy on its premises without using its own stock of drugs. Provides that the structural, equipment, and record retention requirements for a Division VI pharmacy shall be set by rule. Provides that, upon a showing of a possible violation of the Act, the State Board of Pharmacy may compel a pharmacy practice licensee or applicant for licensure to submit to a mental examination, physical examination, or both, as required by and at the expense of the Department of Financial and Professional Regulation. Provides that failure to submit to a mental or physical examination when directed is grounds for license suspension. Provides that if the Board finds an individual unable to practice because of reasons set forth in the Act, the Board must require that individual to submit to care, counseling, or treatment by a physician or clinical psychologist approved by the Board, as a condition, term, or restriction for continued, restored, or renewed licensure to practice. Effective immediately.

LRB094 03782 RAS 33792 b

FISCAL NOTE ACT MAY APPLY

1 AN ACT concerning regulation.

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 14, 15, 18, and 30 as follows:
- 6 (225 ILCS 85/14) (from Ch. 111, par. 4134)
- 7 (Section scheduled to be repealed on January 1, 2008)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) other than a Division VI pharmacy, 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
- 2 balance equipped with balance indicator and with mechanical
- 3 means of arresting the oscillations of the mechanism and which
- 4 balance shall be sensitive to 0.5 grain (32 mg) or less or an
- 5 alternative weighing device as approved by the Department, and
- 6 such other measuring devices as may be necessary for the
- 7 conduct of the practice of pharmacy.
- 8 The provisions of this Section with regard to 300 square
- 9 feet of space shall apply to any pharmacy which is opened after
- 10 the effective date of this Act. Nothing shall require a
- 11 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.
- The structural and equipment requirements for a Division VI
- pharmacy shall be set by rule.
- 16 (Source: P.A. 92-880, eff. 1-1-04.)
- 17 (225 ILCS 85/15) (from Ch. 111, par. 4135)
- 18 (Section scheduled to be repealed on January 1, 2008)
- 19 Sec. 15. Pharmacy requirements. It shall be unlawful for
- 20 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
- 22 conducted, unless:
- 23 (a) It has a licensed pharmacist, authorized to practice
- 24 pharmacy in this State under the provisions of this Act, on
- 25 duty whenever the practice of pharmacy is conducted;
- 26 (b) Security provisions for all drugs and devices, as
- 27 determined by rule of the Department, are provided during the
- absence from the licensed pharmacy of all licensed pharmacists.
- 29 Maintenance of security provisions is the responsibility of the
- 30 licensed registered pharmacist in charge; and
- 31 (c) The pharmacy is licensed under this Act to do business.
- The Department shall, by rule, provide requirements for
- 33 each division of pharmacy license and shall, as well provide
- 34 guidelines for the designation of a registered pharmacist in
- 35 charge for each division.

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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 Mental Health Department of 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 located in Illinois and providing pharmaceutical care to patients of institutions maintaining a Division III pharmacy on its premises without using its own stock of drugs. The pharmaceutical care shall only be given in conjunction with the Division III pharmacy. No services shall be provided to the public. Each Division VI

- 1 pharmacy shall file with the Department a notarized statement
- 2 identifying the institutions to which it provides services
- 3 within 10 days of providing services. A pharmacy maintaining a
- 4 <u>Division I, II, or IV license may not apply for a Division VI</u>
- 5 <u>license</u>. Nothing in this paragraph shall constitute a change to
- 6 the practice of pharmacy as defined in Section 3.
- 7 The Director may waive the requirement for a pharmacist to
- 8 be on duty at all times for State facilities not treating human
- 9 ailments.
- 10 It shall be unlawful for any person, who is not a licensed
- 11 pharmacy or health care facility, to purport to be such or to
- 12 use in name, title, or sign designating, or in connection with
- 13 that place of business, any of the words: "pharmacy",
- "pharmacist", "pharmacy department", "apothecary", "druggist",
- 15 "drug", "drugs", "medicines", "medicine store", "drug
- 16 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
- 21 shall constitute a separate offense under this Act.
- The holder of any license or certificate of registration
- 23 shall conspicuously display it in the pharmacy in which he is
- 24 engaged in the practice of pharmacy. The registered pharmacist
- 25 in charge shall conspicuously display his name in such
- 26 pharmacy. The pharmacy license shall also be conspicuously
- 27 displayed.
- 28 (Source: P.A. 92-880, eff. 1-1-04.)
- 29 (225 ILCS 85/18) (from Ch. 111, par. 4138)
- 30 (Section scheduled to be repealed on January 1, 2008)
- 31 Sec. 18. Record retention.
- 32 (a) Except as provided in subsection (b), there shall be
- 33 kept in every drugstore or pharmacy a suitable book, file, or
- 34 electronic record keeping system in which shall be preserved
- for a period of not less than 5 years the original of every

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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

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.

31 <u>(b) The record retention requirements for a Division VI</u> 32 pharmacy shall be set by rule.

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

34 (225 ILCS 85/30) (from Ch. 111, par. 4150)

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

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- Sec. 30. (a) In accordance with Section 11 of this Act, the
 Department may refuse to issue, restore, or renew, or may
 revoke, suspend, place on probation, reprimand or take other
 disciplinary action as the Department may deem proper with
 regard to any license or certificate of registration for any
 one or combination of the following causes:
- 7 1. Material misstatement in furnishing information to the Department.
 - 2. Violations of this Act, or the rules promulgated hereunder.
 - 3. Making any misrepresentation for the purpose of obtaining licenses.
 - 4. A pattern of conduct which demonstrates incompetence or unfitness to practice.
 - 5. Aiding or assisting another person in violating any provision of this Act or rules.
 - 6. Failing, within 60 days, to respond to a written request made by the Department for information.
 - 7. Engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public.
 - 8. Discipline by another U.S. jurisdiction or foreign nation, if at least one of the grounds for the discipline is the same or substantially equivalent to those set forth herein.
 - 9. Directly or indirectly giving to or receiving from any person, firm, corporation, partnership or association any fee, commission, rebate or other form of compensation for any professional services not actually or personally rendered.
 - 10. A finding by the Department that the licensee, after having his license placed on probationary status has violated the terms of probation.
 - 11. Selling or engaging in the sale of drug samples provided at no cost by drug manufacturers.
 - 12. Physical illness, including but not limited to,

- deterioration through the aging process, or loss of motor skill which results in the inability to practice the profession with reasonable judgment, skill or safety.
 - 13. A finding that licensure or registration has been applied for or obtained by fraudulent means.
 - 14. The applicant, or licensee has been convicted in state or federal court of any crime which is a felony or any misdemeanor related to the practice of pharmacy, of which an essential element is dishonesty.
 - 15. Habitual or excessive use or addiction to alcohol, narcotics, stimulants or any other chemical agent or drug which results in the inability to practice with reasonable judgment, skill or safety.
 - 16. Willfully making or filing false records or reports in the practice of pharmacy, including, but not limited to false records to support claims against the medical assistance program of the Department of Public Aid under the Public Aid Code.
 - 17. Gross and willful overcharging for professional services including filing false statements for collection of fees for which services are not rendered, including, but not limited to, filing false statements for collection of monies for services not rendered from the medical assistance program of the Department of Public Aid under the Public Aid Code.
 - 18. Repetitiously dispensing prescription drugs without receiving a written or oral prescription.
 - 19. Upon a finding of a substantial discrepancy in a Department audit of a prescription drug, including controlled substances, as that term is defined in this Act or in the Illinois Controlled Substances Act.
 - 20. Physical illness which results in the inability to practice with reasonable judgment, skill or safety, or mental incompetency as declared by a court of competent jurisdiction.
 - 21. Violation of the Health Care Worker Self-Referral

1 Act.

- 22. Failing to sell or dispense any drug, medicine, or poison in good faith. "Good faith", for the purposes of this Section, has the meaning ascribed to it in subsection (u) of Section 102 of the Illinois Controlled Substances Act.
- 23. Interfering with the professional judgment of a pharmacist by any registrant under this Act, or his or her agents or employees.
- (b) The Department may refuse to issue or may suspend the license or registration of any person who fails to file a return, or to pay the tax, penalty or interest shown in a filed return, or to pay any final assessment of tax, penalty or interest, as required by any tax Act administered by the Illinois Department of Revenue, until such time as the requirements of any such tax Act are satisfied.
- (c) The Department shall revoke the license or certificate of registration issued under the provisions of this Act or any prior Act of this State of any person who has been convicted a second time of committing any felony under the Illinois Controlled Substances Act, or who has been convicted a second time of committing a Class 1 felony under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A person whose license or certificate of registration issued under the provisions of this Act or any prior Act of this State is revoked under this subsection (c) shall be prohibited from engaging in the practice of pharmacy in this State.
- (d) In any order issued in resolution of a disciplinary proceeding, the Board may request any licensee found guilty of a charge involving a significant violation of subsection (a) of Section 5, or paragraph 19 of Section 30 as it pertains to controlled substances, to pay to the Department a fine not to exceed \$2,000.
- 34 (e) In any order issued in resolution of a disciplinary 35 proceeding, in addition to any other disciplinary action, the 36 Board may request any licensee found guilty of noncompliance

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1 with the continuing education requirements of Section 12 to pay 2 the Department a fine not to exceed \$1000.

- (f) The Department shall issue quarterly to the Board a status of all complaints related to the profession received by the Department.
- (g) In enforcing this Section, the Board may, upon a showing of a possible violation of this Act, compel a licensee or applicant to submit to a mental or physical examination, or both, as required by and at the expense of the Department. The examining physicians or clinical psychologists shall be those specifically designated by the Board. The Board or the Department may order (i) the examining physician to present testimony concerning the mental or physical examination of a licensee or applicant or (ii) the examining clinical psychologist to present testimony concerning the mental examination of a licensee or applicant. No information shall be excluded by reason of any common law or statutory privilege relating to communications between a licensee or applicant and the examining physician or clinical psychologist. An 20 individual to be examined may have, at his or her own expense, another physician or clinical psychologist of his or her choice present during all aspects of the examination. Failure of an 22 23 individual to submit to a mental or physical examination, when directed, is grounds for suspension of his or her license. The license must remain suspended until the individual submits to 25 the examination or the Board finds, after notice and hearing, 26 that the refusal to submit to the examination was with 28 reasonable cause.

If the Board finds an individual unable to practice because of the reasons set forth in this Section, the Board must require the individual to submit to care, counseling, or treatment by a physician or clinical psychologist approved by the Board as a condition, term, or restriction for continued, restored, or renewed licensure to practice. In lieu of care, counseling, or treatment, the Board may recommend that the Department immediately suspend or revoke the license of the

- 1 <u>individual or otherwise discipline the licensee.</u>
- 2 Any individual whose license was issued, continued,
- 3 restored, or renewed subject to conditions, terms, or
- 4 <u>restrictions</u>, as provided for in this Section, or any
- 5 <u>individual who was disciplined or placed on supervision</u>
- 6 pursuant to this Section must be referred to the Director for a
- 7 <u>determination as to whether the person shall have his or her</u>
- 8 <u>license suspended immediately, pending a hearing by the Board.</u>
- 9 (Source: P.A. 92-880, eff. 1-1-04.)
- 10 Section 99. Effective date. This Act takes effect upon
- 11 becoming law.