HB5581

LRB09720467CELb

97TH GENERAL ASSEMBLY

State of Illinois

2011 and 2012

HB5581

Introduced 2/15/2012, by Rep. Ann Williams - Edward J. Acevedo

SYNOPSIS AS INTRODUCED:

225 ILCS 85/25.3 new
225 ILCS 85/30 from Ch. 111, par. 4150

Amends the Pharmacy Practice Act. Provides that a biosimilar product determined to be interchangeable by the United States Food and Drug Administration shall be available for substitution in the State in accordance with the Act and the Illinois Food, Drug and Cosmetic Act, provided that each manufacturer submits to the Director of the Department of Public Health a notification containing product interchangeability information as a prerequisite to product substitution when they have FDA product approval, as interchangeable, and, in any event, the information shall be submitted no later than 60 days prior to product substitution in the State. Sets forth provisions concerning prescription forms. Provides that a pharmacy may substitute a prescription biosimilar product for a prescribed product only under certain circumstances. Sets forth provisions concerning publication and compliance. Provides that a violation of the biosimilar products provision shall be include in the list of causes for which the Department of Financial and Professional Regulation may take disciplinary or non-disciplinary action as the Department may deem proper. Effective January 1, 2013.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

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 is amended by changing Section 30 and by adding Section 25.3 as follows:

(225 ILCS 85/25.3 new)

Sec. 25.3. Biosimilar products.

(a) For the purposes of this Section:

"Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" have the meanings that apply to those terms under Section 351 of the Public Health Service Act (42 U.S.C. 262).

"Prescription", with respect to a biological product, means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(b) A biosimilar product determined to be interchangeable by the United States Food and Drug Administration (FDA) shall be available for substitution in this State in accordance with this Act and the Illinois Food, Drug and Cosmetic Act, provided that each manufacturer submits to the Director of the Department of Public Health a notification containing product interchangeability information as a prerequisite to product

substitution when they have FDA product approval, as interchangeable, and, in any event, the information shall be submitted no later than 60 days prior to product substitution in this State. On the prescription forms of prescribers shall be placed a signature line and the words "may not substitute". The prescriber, in his or her own handwriting, shall place a mark beside the words "may not substitute" to direct the pharmacist in the dispensing of the prescription. Preprinted or rubber stamped marks, or other deviations from the prescription format established pursuant to this Section, shall not be permitted. The prescriber shall sign the form in his or her own handwriting to authorize the issuance of the prescription.

(c) A pharmacy may substitute a prescription biosimilar product for a prescribed product only if:

(1) the biosimilar product has been determined by the FDA to be interchangeable with the prescribed product for the specified indicated use;

(2) the prescribing physician does not designate in writing on the prescription that substitution is prohibited;

(3) the patient (or patient's authorized representative) provides written consent for the substitution;

(4) the pharmacist notifies the prescriber in writing within 24 hours after the substitution; and

(5) the pharmacy and the prescribing physician retain a

written record of the biosimilar substitution for a period of no less than 5 years.

(d) The Department of Public Health shall maintain on its public website a current list of biosimilar biological products determined to be interchangeable pursuant to subsections (b) and (c) of this Section.

(e) The Illinois Board of Pharmacy shall adopt rules for compliance with this Section, under which a pharmacy that violates subsections (b) and (c) of this Section shall be subject to a specified civil monetary penalty as provided in Section 30 of this Act.

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

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

Sec. 30. Refusal, revocation, or suspension.

(a) The Department may refuse to issue or renew, or may revoke a license or registration, or may suspend, place on probation, fine, or take any disciplinary or non-disciplinary action as the Department may deem proper, including fines not to exceed $10,000 for each violation, with regard to any licensee or registrant for any one or combination of the following causes:

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 unprofessional, dishonorable, or unethical 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. Nothing in this item 9 affects any bona fide independent contractor or employment arrangements among health care professionals, health facilities, health care providers, or other entities, except as otherwise prohibited by law. Any employment arrangements may include provisions for compensation, health insurance, pension, or other employment benefits for the provision of services

within the scope of the licensee's practice under this Act. Nothing in this item 9 shall be construed to require an employment arrangement to receive professional fees for services 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 or entered a plea of guilty, nolo contendere, or the equivalent in a state or federal court to any crime which is a felony or any misdemeanor related to the practice of pharmacy or 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 Healthcare and Family Services (formerly 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 Healthcare and Family Services (formerly Department of Public Aid) under the Public Aid Code.

18. Dispensing prescription drugs without receiving a written or oral prescription in violation of law.

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 or mental illness or any other impairment or disability, including without limitation deterioration through the aging process or loss of motor skills that results in the inability to practice with reasonable judgment, skill or safety, or mental incompetence, as declared by a court of competent jurisdiction.

21. Violation of the Health Care Worker Self-Referral

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. "Good faith", as used in this item (22), shall not be limited to the sale or dispensing of controlled substances, but shall apply to all prescription drugs.

23. Interfering with the professional judgment of a pharmacist by any registrant under this Act, or his or her agents or employees.

24. Failing to report within 60 days to the Department any adverse final action taken against a pharmacist, pharmacist technician, or certified pharmacist technician by another licensing jurisdiction in any other state or any territory of the United States or any foreign jurisdiction, any governmental agency, any law enforcement agency, or any court for acts or conduct similar to acts or conduct that would constitute grounds for discipline as defined in this Section.

25. Failing to comply with a subpoena issued in accordance with Section 35.5 of this Act.

26. Disclosing protected health information in violation of any State or federal law.

27. Failing to comply with Section 25.3 of this Act.

(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) Fines may be imposed in conjunction with other forms of disciplinary action, but shall not be the exclusive disposition of any disciplinary action arising out of conduct resulting in death or injury to a patient. Fines shall be paid within 60 days or as otherwise agreed to by the Department. Any funds collected from such fines shall be deposited in the Illinois State Pharmacy Disciplinary Fund.

(e) The entry of an order or judgment by any circuit court establishing that any person holding a license or certificate

under this Act is a person in need of mental treatment operates as a suspension of that license. A licensee may resume his or her practice only upon the entry of an order of the Department based upon a finding by the Board that he or she has been determined to be recovered from mental illness by the court and upon the Board's recommendation that the licensee be permitted to resume his or her practice.

(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 or the Department, upon a showing of a possible violation, may compel any licensee or applicant for licensure under this Act to submit to a mental or physical examination or both, as required by and at the expense of the Department. The examining physician, or multidisciplinary team involved in providing physical and mental examinations led by a physician consisting of one or a combination of licensed physicians, licensed clinical psychologists, licensed clinical social workers, licensed clinical professional counselors, and other professional and administrative staff, shall be those specifically designated by the Department. The Board or the Department may order the examining physician or any member of the multidisciplinary team to present testimony concerning this mental or physical examination of the licensee or applicant. No information, report, or other documents in any way related to the

examination shall be excluded by reason of any common law or statutory privilege relating to communication between the licensee or applicant and the examining physician or any member of the multidisciplinary team. The individual to be examined may have, at his or her own expense, another physician of his or her choice present during all aspects of the examination. Failure of any individual to submit to a mental or physical examination when directed shall be grounds for suspension of his or her license until such time as the individual submits to the examination if the Board finds, after notice and hearing, that the refusal to submit to the examination was without reasonable cause. If the Board finds a pharmacist, certified pharmacy technician, or pharmacy technician unable to practice because of the reasons set forth in this Section, the Board shall require such pharmacist, certified pharmacy technician, or pharmacy technician to submit to care, counseling, or treatment by physicians or other appropriate health care providers approved or designated by the Board as a condition for continued, reinstated, or renewed licensure to practice. Any pharmacist, certified pharmacy technician, or pharmacy technician whose license was granted, continued, reinstated, renewed, disciplined, or supervised, subject to such terms, conditions, or restrictions, and who fails to comply with such terms, conditions, or restrictions or to complete a required program of care, counseling, or treatment, as determined by the chief pharmacy coordinator or a deputy pharmacy coordinator,

shall be referred to the Secretary for a determination as to whether the licensee shall have his or her license suspended immediately, pending a hearing by the Board. In instances in which the Secretary immediately suspends a license under this subsection (g), a hearing upon such person's license must be convened by the Board within 15 days after such suspension and completed without appreciable delay. The Board shall have the authority to review the subject pharmacist's, certified pharmacy technician's, or pharmacy technician's record of treatment and counseling regarding the impairment.

(Source: P.A. 95-331, eff. 8-21-07; 95-689, eff. 10-29-07; 96-673, eff. 1-1-10; 96-1482, eff. 11-29-10.)

Section 99. Effective date. This Act takes effect January 1, 2013.