SB2150

LRB095 19510 KBJ 45812 b

95TH GENERAL ASSEMBLY

State of Illinois

2007 and 2008

SB2150

Introduced 2/14/2008, by Sen. David Koehler

SYNOPSIS AS INTRODUCED:

See Index

Amends the Medical Practice Act of 1987. Provides that any person licensed under the Act shall dispense drugs or medicine with a label indicating the name of the patient except in the practice of expedited partner therapy for the treatment of sexually transmissible diseases. Makes corresponding changes in the Pharmacy Practice Act and the Illinois Food, Drug and Cosmetic Act. Amends the Illinois Sexually Transmissible Disease Control Act. Adds a definition of "health care professional" and "expedited partner therapy". Provides that the Department of Public Health shall establish and administer an expedited partner therapy program for the treatment of persons with sexually transmissible diseases, as determined by the Department, taking into account the recommendations of the U.S. Centers for Disease Control and other nationally recognized medical authorities. Provides that notwithstanding any other provision of law, a health care professional who makes a clinical diagnosis of chlamydia, gonorrhea, or other sexually transmissible diseases, as determined by the Department, may prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to the infected person's sexual partner or partners for the treatment of the sexually transmissible disease without physical examination of the partner or partners, if in the judgment of the health care professional, the partner is unlikely or unable to present for comprehensive healthcare, including evaluation, testing, and treatment for sexually transmissible diseases. Provides that the health care professional shall provide counseling for the patient and written materials to be given by the patient to the partner or partners. Makes other changes.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

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

Section 5. The Medical Practice Act of 1987 is amended by changing Section 33 as follows:

(225 ILCS 60/33) (from Ch. 111, par. 4400-33)

(Section scheduled to be repealed on December 31, 2008)

Sec. 33. Any person licensed under this Act to practice medicine in all of its branches shall be authorized to purchase legend drugs requiring an order of a person authorized to prescribe drugs, and to dispense such legend drugs in the regular course of practicing medicine. The dispensing of such legend drugs shall be the personal act of the person licensed under this Act and may not be delegated to any other person not licensed under this Act or the Pharmacy Practice Act unless such delegated dispensing functions are under the direct supervision of the physician authorized to dispense legend drugs. Except when dispensing manufacturers' samples or other legend drugs in a maximum 72 hour supply, persons licensed under this Act shall maintain a book or file of prescriptions as required in the Pharmacy Practice Act. Any person licensed under this Act who dispenses any drug or medicine shall dispense such drug or medicine in good faith and shall affix to

the box, bottle, vessel or package containing the same a label indicating (a) the date on which such drug or medicine is dispensed; (b) the name of the patient, except in the practice of expedited partner therapy for the treatment of sexually transmissible diseases; (c) the last name of the person dispensing such drug or medicine; (d) the directions for use thereof; and (e) the proprietary name or names or, if there are none, the established name or names of the drug or medicine, the dosage and quantity, except as otherwise authorized by regulation of the Department of Professional Regulation. The foregoing labeling requirements shall not apply to drugs or medicines in a package which bears a label of the manufacturer containing information describing its contents which is in compliance with requirements of the Federal Food, Drug, and Cosmetic Act and the Illinois Food, Drug, and Cosmetic Act. "Drug" and "medicine" have the meaning ascribed to them in the Pharmacy Practice Act, as now or hereafter amended; "good faith" has the meaning ascribed to it in subsection (v) of Section 102 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended. "Expedited partner therapy" has the same meaning ascribed to it in the Illinois Sexually Transmissible Disease Control Act.

Prior to dispensing a prescription to a patient, the physician shall offer a written prescription to the patient which the patient may elect to have filled by the physician or any licensed pharmacy.

A violation of any provision of this Section shall constitute a violation of this Act and shall be grounds for disciplinary action provided for in this Act.

(Source: P.A. 95-689, eff. 10-29-07.)

Section 10. The Pharmacy Practice Act is amended by changing Sections 3 and 22 as follows:

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

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

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 pharmacist 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, advanced practice nurses, physician assistants, veterinarians, podiatrists, or 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", "Dispensary", "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 (1) the interpretation and the provision of assistance in the monitoring, evaluation, and implementation of prescription drug orders; (2) the dispensing of prescription drug orders; (3) participation in drug and device selection; (4) drug administration limited to the administration of oral, topical, injectable, and inhalation as follows: in the context of patient education on the proper use or delivery of medications; vaccination of patients 14 years of age and older pursuant to a valid prescription or standing order, by a physician licensed to practice medicine in all its branches, upon completion of appropriate training, including how to address contraindications and adverse reactions set forth by rule, with notification to the patient's physician and appropriate record retention, or pursuant to hospital pharmacy and therapeutics committee policies and procedures; (5) drug regimen review; (6) drug or drug-related research; (7) the provision of patient counseling; (8) the practice of telepharmacy; (9) the provision of those acts or services necessary to provide pharmacist care; (10) medication therapy management; and (11) the responsibility for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of required records. A pharmacist who performs any of the acts defined as the practice of pharmacy in this State must be

actively licensed as a pharmacist under this Act.

(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 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, except in the practice of expedited partner therapy for the treatment of sexually transmissible diseases; (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 Financial and Professional Regulation.

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

(i) "Secretary" means the Secretary of Financial and

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" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container

appropriately labeled for subsequent administration to or use by a patient in accordance with applicable State and federal laws and regulations. "Dispense" or "dispensing" 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" or "dispensing" 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) "Nonresident pharmacy" means a pharmacy that is located in a state, commonwealth, or territory of the United States, other than Illinois, that delivers, dispenses, or distributes, through the United States Postal Service, commercially acceptable parcel delivery service, or other common carrier, to Illinois residents, any substance which requires a prescription.

(o) "Compounding" means the preparation and mixing of components, excluding flavorings, (1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed dispensing

patterns. Commercially available products may be compounded for dispensing to individual patients only if all of the following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs and (ii) the prescribing practitioner has requested that the drug be compounded.

(p) (Blank).

(q) (Blank).

(r) "Patient counseling" means the communication between a pharmacist or a pharmacy intern under the 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. "Patient counseling" may include without limitation (1) obtaining a medication history; (2) acquiring a patient's allergies and health conditions; (3) facilitation of the patient's understanding of the intended use of the medication; (4) proper directions for use; (5) significant potential adverse events; (6) potential food-drug interactions; and (7) the need to be compliant with the medication therapy. A pharmacy technician may only participate in the following aspects of patient counseling under the supervision of a pharmacist: (1) obtaining medication history; (2) providing the offer for counseling by a pharmacist or intern; and (3) acquiring a patient's allergies and health conditions.

(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) (Blank).

(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 biometric or electronic identification process as approved by the Department.

(w) "Current usual and customary retail price" means the price that a pharmacy charges to a non-third-party payor .

(x) "Automated pharmacy system" means a mechanical system located within the confines of the pharmacy or remote location that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(y) "Drug regimen review" means and includes the evaluation of prescription drug orders and patient records for (1) known allergies; (2) drug or potential therapy contraindications; (3) reasonable dose, duration of use, and route of administration, taking into consideration factors such as age, gender, and contraindications; (4) reasonable directions for use; (5) potential or actual adverse drug reactions; (6) drug-drug interactions; (7) drug-food interactions; (8) drug-disease contraindications; (9) therapeutic duplication; (10) patient laboratory values when authorized and available; (11) proper utilization (including over or under utilization) and optimum therapeutic outcomes; and (12) abuse and misuse.

(z) "Electronic transmission prescription" means any prescription order for which a facsimile or electronic image of the order is electronically transmitted from a licensed prescriber to a pharmacy. "Electronic transmission prescription" includes both data and image prescriptions.

(aa) "Medication therapy management services" means a distinct service or group of services offered by licensed pharmacists, physicians licensed to practice medicine in all its branches, advanced practice nurses authorized in a written agreement with a physician licensed to practice medicine in all its branches, or physician assistants authorized in guidelines by a supervising physician that optimize therapeutic outcomes for individual patients through improved medication use. In a retail or other non-hospital pharmacy, medication therapy

management services shall consist of the evaluation of prescription drug orders and patient medication records to resolve conflicts with the following:

(1) known allergies;

(2) drug or potential therapy contraindications;

(3) reasonable dose, duration of use, and route of administration, taking into consideration factors such as age, gender, and contraindications;

(4) reasonable directions for use;

(5) potential or actual adverse drug reactions;

(6) drug-drug interactions;

(7) drug-food interactions;

(8) drug-disease contraindications;

(9) identification of therapeutic duplication;

(10) patient laboratory values when authorized and available;

(11) proper utilization (including over or under utilization) and optimum therapeutic outcomes; and

(12) drug abuse and misuse.

"Medication therapy management services" includes the following:

(1) documenting the services delivered and communicating the information provided to patients' prescribers within an appropriate time frame, not to exceed 48 hours;

(2) providing patient counseling designed to enhance a

patient's understanding and the appropriate use of his or her medications; and

(3) providing information, support services, and resources designed to enhance a patient's adherence with his or her prescribed therapeutic regimens.

"Medication therapy management services" may also include patient care functions authorized by a physician licensed to practice medicine in all its branches for his or her identified patient or groups of patients under specified conditions or limitations in a standing order from the physician.

"Medication therapy management services" in a licensed hospital may also include the following:

(1) reviewing assessments of the patient's health status; and

(2) following protocols of a hospital pharmacy and therapeutics committee with respect to the fulfillment of medication orders.

(bb) "Pharmacist care" means the provision by a pharmacist of medication therapy management services, with or without the dispensing of drugs or devices, intended to achieve outcomes that improve patient health, quality of life, and comfort and enhance patient safety.

(cc) "Protected health information" means individually identifiable health information that, except as otherwise provided, is:

(1) transmitted by electronic media;

(2) maintained in any medium set forth in the definition of "electronic media" in the federal Health Insurance Portability and Accountability Act; or

(3) transmitted or maintained in any other form or medium.

"Protected health information" does not include individually identifiable health information found in:

(1) education records covered by the federal Family Educational Right and Privacy Act; or

(2) employment records held by a licensee in its role as an employer.

(dd) "Standing order" means a specific order for a patient or group of patients issued by a physician licensed to practice medicine in all its branches in Illinois.

(ee) "Address of record" means the address recorded by the Department in the applicant's or licensee's application file or license file, as maintained by the Department's licensure maintenance unit.

(ff) "Home pharmacy" means the location of a pharmacy's primary operations.

(Source: P.A. 94-459, eff. 1-1-06; 95-689, eff. 10-29-07.)

(225 ILCS 85/22) (from Ch. 111, par. 4142)

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

Sec. 22. Except only in the case of a drug, medicine or poison which is lawfully sold or dispensed, at retail, in the

original and unbroken package of the manufacturer, packer, or distributor thereof, and which package bears the original label thereon showing the name and address of the manufacturer, packer, or distributor thereof, and the name of the drug, medicine, or poison therein contained, and the directions for its use, no person shall sell or dispense, at retail, any drug, medicine, or poison, without affixing to the box, bottle, vessel, or package containing the same, a label bearing the name of the article distinctly shown, and the directions for its use, with the name and address of the pharmacy wherein the same is sold or dispensed. However, in the case of a drug, medicine, or poison which is sold or dispensed pursuant to a prescription of a physician licensed to practice medicine in all of its branches, licensed dentist, licensed veterinarian, licensed podiatrist, or therapeutically or diagnostically certified optometrist authorized by law to prescribe drugs or medicines or poisons, the label affixed to the box, bottle, vessel, or package containing the same shall show: (a) the name and address of the pharmacy wherein the same is sold or dispensed; (b) the name or initials of the person, authorized to practice pharmacy under the provisions of this Act, selling or dispensing the same, (c) the date on which such prescription was filled; (d) the name of the patient<u>, except in the practice of expedited partner therapy for the treatment of sexually transmissible diseases</u>; (e) the serial number of such prescription as filed in the prescription files; (f) the last

name of the practitioner who prescribed such prescriptions; (g) the directions for use thereof as contained in such prescription; and (h) the proprietary name or names or the established name or names of the drugs, the dosage and quantity, except as otherwise authorized by regulation of the Department.

(Source: P.A. 95-689, eff. 10-29-07.)

Section 15. The Illinois Sexually Transmissible Disease Control Act is amended by changing Sections 3 and 6 as follows:

(410 ILCS 325/3) (from Ch. 111 1/2, par. 7403)

Sec. 3. Definitions. As used in this Act, unless the context clearly requires otherwise:

(1) "Department" means the Department of Public Health.

(2) "Local health authority" means the full-time official health department of board of health, as recognized by the Department, having jurisdiction over a particular area.

(3) "Sexually transmissible disease" means a bacterial, viral, fungal or parasitic disease, determined by rule of the Department to be sexually transmissible, to be a threat to the public health and welfare, and to be a disease for which a legitimate public interest will be served by providing for regulation and treatment. In considering which diseases are to be designated sexually transmissible diseases, the Department shall consider such diseases as chancroid, gonorrhea,

granuloma inguinale, lymphogranuloma venereum, genital herpes simplex, chlamydia, nongonococcal urethritis (NGU), pelvic inflammatory disease (PID)/Acute Salpingitis, syphilis, Acquired Immunodeficiency Syndrome (AIDS), and Human Immunodeficiency Virus (HIV) for designation, and shall consider the recommendations and classifications of the Centers for Disease Control and other nationally recognized medical authorities. Not all diseases that are sexually transmissible need be designated for purposes of this Act.

(4) "Health care professional" means a physician licensed to practice medicine in all its branches, a physician assistant who has been delegated the provision of health services by his or her supervising physician, or an advanced practice registered nurse who has a written collaborative agreement with a collaborating physician that authorizes the provision of health services.

(5) "Expedited partner therapy" means to prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to the partner or partners of persons clinically diagnosed as infected with a sexually transmissible disease, without physical examination of the partner or partners.

(Source: P.A. 85-1209.)

(410 ILCS 325/6) (from Ch. 111 1/2, par. 7406)

Sec. 6. Physical examination and treatment.

(a) Subject to the provisions of subsection (c) of this Section, the Department and its authorized representatives may examine or cause to be examined persons reasonably believed to be infected with or to have been exposed to a sexually transmissible disease.

(b) Subject to the provisions of subsection (c) of this Section, persons with a sexually transmissible disease shall report for complete treatment to a physician licensed under the provisions of the Medical Practice Act of 1987, or shall submit to treatment at a facility provided by a local health authority or other public facility, as the Department shall require by rule or regulation until the disease is noncommunicable or the Department determines that the person does not present a real and present danger to the public health. This subsection (b) shall not be construed to require the Department or local health authorities to pay for or provide such treatment.

(c) No person shall be apprehended, examined or treated for a sexually transmissible disease against his will, under the provisions of this Act, except upon the presentation of a warrant duly authorized by a court of competent jurisdiction. In requesting the issuance of such a warrant the Department shall show by a preponderance of evidence that the person is infectious and that a real and present danger to the public health and welfare exists unless such warrant is issued and shall show that all other reasonable means of obtaining compliance have been exhausted and that no other less

restrictive alternative is available. The court shall require any proceedings authorized by this subsection (c) to be conducted in camera. A record shall be made of such proceedings but shall be sealed, impounded and preserved in the records of the court, to be made available to the reviewing court in the event of an appeal.

(d) Any person who knowingly or maliciously disseminates any false information or report concerning the existence of any sexually transmissible disease under this Section is guilty of a Class A misdemeanor.

(e) The Department shall establish and administer an expedited partner therapy program for the treatment of persons with sexually transmissible diseases, as determined by the Department, taking into account the recommendations of the U.S. Centers for Disease Control and other nationally recognized medical authorities.

(1) Notwithstanding any other provision of law, a health care professional who makes a clinical diagnosis of chlamydia, gonorrhea, or other sexually transmissible diseases, as determined by the Department, may prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to the infected person's sexual partner or partners for the treatment of the sexually transmissible disease without physical examination of the partner or partners, if in the judgment of the health care professional, the partner is unlikely or unable to present

for comprehensive healthcare, including evaluation, testing, and treatment for sexually transmissible diseases.

(2) Healthcare professionals who practice expedited partner therapy shall comply with Sections 4 and 5 of this Act. The Department shall provide informational materials for persons who are repeatedly diagnosed with sexually transmissible diseases.

(3) The health care professional shall provide counseling for the patient and written materials to be given by the patient to the partner or partners that includes at a minimum information about the following:

(A) the medications and dosage provided and allergy and side effect warnings;

(B) treatment and prevention of sexually transmissible diseases;

(C) the requirement of abstinence for a period of time after treatment to prevent infection or re-infecting others;

(D) the importance for the partner or partners of the patient to receive examination and testing for HIV and other sexually transmissible diseases, and the essential need for an immediate examination if a woman is or may be pregnant, and referral for such services;

(E) notification of the risk to self, others, and the public health if the sexually transmissible

disease is not completely and successfully treated;

(F) the responsibility of the partner or partners to inform his or her sex partners of the risk of sexually transmissible disease infection and the importance of prompt examination and treatment; and

(G) other information as deemed necessary by the Department.

The Department shall develop and disseminate model informational materials in electronic or other formats. The Department may offer educational programs about expedited partner therapy for health care professionals and pharmacists licensed under the Pharmacy Practice Act.

(Source: P.A. 90-14, eff. 7-1-97.)

Section 20. The Illinois Food, Drug and Cosmetic Act is amended by changing Section 2.36 as follows:

(410 ILCS 620/2.36) (from Ch. 56 1/2, par. 502.36)

Sec. 2.36. "Prescription" means and includes any order for drugs or medical devices, written, facsimile, or verbal by a physician licensed to practice medicine in all its branches, dentist, veterinarian, or podiatrist containing the following: (1) name of the patient, except in the practice of expedited partner therapy for the treatment of sexually transmitted diseases; (2) date when prescription was given; (3) name and strength of drug or description of the medical device

prescribed; (4) quantity, (5) directions for use, (6) prescriber's name, address and signature, and (7) DEA number where required, for controlled substances.

(Source: P.A. 89-202, eff. 7-21-95.)

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