HB1077

LRB095 03803 RAS 23834 b

95TH GENERAL ASSEMBLY

State of Illinois

2007 and 2008

HB1077

Introduced 2/8/2007, by Rep. Sara Feigenholtz - David E. Miller - Julie Hamos

SYNOPSIS AS INTRODUCED:

225 ILCS 60/54.5
225 ILCS 85/22b new
410 ILCS 620/3.21 from Ch. 56 1/2, par. 503.21

Amends the Pharmacy Practice Act of 1987. Allows pharmacists to initiate emergency contraception drug therapy in accordance with protocols developed by the pharmacist and an authorized prescriber. Sets forth provisions concerning the protocol, documentation and recordkeeping, pharmacist training and continuing education, and patient profiles and confidentiality. Requires that the Department of Financial and Professional Regulation develop a standardized fact sheet to be provided to the recipient of the emergency contraceptive drugs. Grants rulemaking authority to the Department and requires the Department to adopt emergency rules concerning the administration of the emergency contraception drug therapy provisions. Amends the Medical Practice Act of 1987 and the Illinois Food, Drug and Cosmetic Act to make related changes. Effective immediately.

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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 Medical Practice Act of 1987 is amended by changing Section 54.5 as follows:

(225 ILCS 60/54.5)

(Section scheduled to be repealed on December 31, 2008)

Sec. 54.5. Physician delegation of authority.

(a) Physicians licensed to practice medicine in all its branches may delegate care and treatment responsibilities to a physician assistant under guidelines in accordance with the requirements of the Physician Assistant Practice Act of 1987. A physician licensed to practice medicine in all its branches may enter into supervising physician agreements with no more than 2 physician assistants.

(b) A physician licensed to practice medicine in all its branches in active clinical practice may collaborate with an advanced practice nurse in accordance with the requirements of Title 15 of the Nursing and Advanced Practice Nursing Act. Collaboration is for the purpose of providing medical direction, and no employment relationship is required. A written collaborative agreement shall conform to the requirements of Sections 15-15 and 15-20 of the Nursing and

Advanced Practice Nursing Act. The written collaborative agreement shall be for services the collaborating physician generally provides to his or her patients in the normal course of clinical medical practice. Physician medical direction shall be adequate with respect to collaboration with certified nurse practitioners, certified nurse midwives, and clinical nurse specialists if a collaborating physician:

(1) participates in the joint formulation and joint approval of orders or guidelines with the advanced practice nurse and periodically reviews such orders and the services provided patients under such orders in accordance with accepted standards of medical practice and advanced practice nursing practice;

(2) is on site at least once a month to provide medical direction and consultation; and

(3) is available through telecommunications for consultation on medical problems, complications, or emergencies or patient referral.

(b-1) A physician licensed to practice medicine in all its branches in active clinical practice may collaborate with a pharmacist for the purposes of emergency contraception drug therapy initiation, in accordance with the requirements of Section 22b of the Pharmacy Practice Act of 1987.

(b-5) An anesthesiologist or physician licensed to practice medicine in all its branches may collaborate with a certified registered nurse anesthetist in accordance with

Section 15-25 of the Nursing and Advanced Practice Nursing Act. Medical direction for a certified registered nurse anesthetist shall be adequate if:

(1) an anesthesiologist or a physician participates in the joint formulation and joint approval of orders or guidelines and periodically reviews such orders and the services provided patients under such orders; and

(2) for anesthesia services, the anesthesiologist or physician participates through discussion of and agreement with the anesthesia plan and is physically present and available on the premises during the delivery of anesthesia services for diagnosis, consultation, and treatment of emergency medical conditions. Anesthesia services in a hospital shall be conducted in accordance with Section 10.7 of the Hospital Licensing Act and in an ambulatory surgical treatment center in accordance with Section 6.5 of the Ambulatory Surgical Treatment Center Act.

(b-10) The anesthesiologist or operating physician must agree with the anesthesia plan prior to the delivery of services.

(c) The supervising physician shall have access to the medical records of all patients attended by a physician assistant. The collaborating physician shall have access to the medical records of all patients attended to by an advanced practice nurse.

(d) Nothing in this Act shall be construed to limit the

delegation of tasks or duties by a physician licensed to practice medicine in all its branches to a licensed practical nurse, a registered professional nurse, or other personnel.

(e) A physician shall not be liable for the acts or omissions of a physician assistant or advanced practice nurse solely on the basis of having signed a supervision agreement or guidelines or a collaborative agreement, an order, a standing medical order, a standing delegation order, or other order or guideline authorizing a physician assistant or advanced practice nurse to perform acts, unless the physician has reason to believe the physician assistant or advanced practice nurse lacked the competency to perform the act or acts or commits willful and wanton misconduct.

(Source: P.A. 90-742, eff. 8-13-98; 91-414, eff. 8-6-99.)

Section 10. The Pharmacy Practice Act of 1987 is amended by adding Section 22b as follows:

(225 ILCS 85/22b new)

Sec. 22b. Emergency contraception drug therapy.

(a) The General Assembly finds the following:

(1) Unintended pregnancies are a major public health concern affecting individuals and society in general. Each year, about 3,500,000 unintended pregnancies occur in this country, half of which result from contraceptive failure or inadequate contraceptive technique.

(2) Emergency contraception is a highly cost-effective method of reducing unintended pregnancies and is most effective the earlier it is used. However, there are often significant barriers to women obtaining emergency contraception in a timely manner.

(3) The American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Medical Association, the American Public Health Association, and more than 50 other national organizations support increased access to emergency contraception.

The purpose of this Section is to establish collaborative practice between pharmacists and authorized prescribers that will enable pharmacists with appropriate training and who are working in collaboration with an authorized prescriber to initiate emergency contraception drug therapy in order to increase timely access to emergency contraception.

(b) For the purposes of this Section:

"Authorized prescriber" means a "prescriber", as that term is defined in Section 102 of the Illinois Controlled Substances Act, who is authorized by the laws of this State to prescribe drugs.

"Collaborative agreement" means an arrangement between a pharmacist and an authorized prescriber that authorizes the pharmacist to dispense emergency contraception to either the patients of the authorized prescriber or individuals who are not the patients of the authorized

prescriber.

"Emergency contraception" means a drug that is (i) used after intercourse; (ii) an elevated dose of hormones used to prevent pregnancy; (iii) approved by the United States Food and Drug Administration; and (iv) requires a prescription.

"Protocol" means a written agreement between a pharmacist or group of pharmacists and a licensed physician or group of physicians that delegates prescriptive authority.

"Initiate" means to dispense emergency contraception under a collaborative practice as outlined in this Section.

(c) Notwithstanding any other provision of law, a licensed pharmacist who has completed the training required in this Section may initiate emergency contraception drug therapy in accordance with protocols developed by the pharmacist and an authorized prescriber. Nothing in this Section shall be construed to authorize collaborative practice between a pharmacist and an authorized prescriber for any drugs other than emergency contraception. Collaboration is for the purpose of providing medical direction, and no employment relationship is required.

(d) A pharmacist planning to initiate emergency contraception drug therapy in his or her practice shall have on file at his or her place of practice written protocol. The protocol shall authorize a pharmacist to initiate emergency contraception drug therapy and shall be established and

approved by an authorized prescriber in accordance with rules adopted by the Department. A copy of the written protocol shall be on file with the Department.

(e) The protocol required by subsection (d) of this Section shall include all of the following:

(1) A statement identifying the authorized prescriber and the pharmacist who are parties to the protocol.

(2) A statement that the protocol is limited to the initiation of emergency contraception drug therapy.

(3) A general statement of the procedures, decision criteria, or plan the pharmacist is to follow when initiating emergency contraception drug therapy.

(4) A statement of the activities the pharmacist is to follow in the course of initiating emergency contraception drug therapy, including documentation of decisions made and a plan for communication or feedback to the licensed physician concerning specific decisions made. Documentation may occur on the prescriptive record, patient profile, patient medical chart, or in a separate log book.

(5) A statement that describes appropriate mechanisms for reporting to the authorized prescriber monitoring activities and results.

(6) A statement that describes how the licensed physician will review the documentation and records made by the pharmacist and that such review shall occur at least

once every 3 months.

(7) A time period, not to exceed 2 years, during which the written protocol will be in effect.

(f) Documentation related to the protocol must be maintained for at least 3 years.

(g) The authorized prescriber shall review the documentation and records made by the pharmacist and this review shall occur at least once every 3 months during the time in which the protocol is in effect.

(h) The protocol may be terminated upon written notice by the authorized prescriber or pharmacist. The pharmacist shall notify the Department in writing within 30 days after such termination.

(i) The protocol shall be limited in duration to not more than 2 years but shall be renewable pursuant to agreement between the authorized prescriber and the pharmacist.

(j) Any modification to the protocol must be approved by the Department as required by this Section for new protocols.

(k) The pharmacist must successfully complete a course of training in the subject area of emergency contraception drug therapy provided by (i) the Department of Public Health, (ii) the American Council on Pharmaceutical Education (ACPE), or (iii) a similar health authority, community organization, or professional body approved by the Department.

Training must include study materials and instruction in the following content areas:

(1) current standards for prescribing emergency contraception drug therapy;

(2) indications for the use of emergency contraception drug therapy;

(3) interviewing the patient to establish need for emergency contraception drug therapy, including sensitive communication with the patient;

(4) patient counseling regarding the safety, efficacy, and potential adverse effects of emergency contraception;

(5) referring patient for follow-up care with a health care provider;

(6) informed consent;

(7) documentation and record management; and

(8) management of adverse events, including identification, appropriate response, documentation, and reporting.

(l) Any pharmacist initiating emergency contraception drug therapy shall complete approved continuing education related to emergency contraception drug therapy every 2 years.

(m) For each emergency contraception drug therapy initiated pursuant to this Section, the pharmacist shall provide the recipient of the emergency contraceptive drugs with a standardized fact sheet developed by the Department that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical follow-up and referral information, information on

sexual assault and referral information, and other appropriate information.

In developing the fact sheet required in this subsection, the Department shall consult with and solicit input from the Department of Public Health, the American College of Obstetricians and Gynecologists, Illinois Pharmacists Association, Planned Parenthood, and other relevant health care or professional organizations. After this consultation and review, the Department may use, as its standardized fact sheet, an existing publication developed by nationally recognized medical organizations.

The Department may post the standardized fact sheet on its web site for use by pharmacists who initiate emergency contraception drug therapy.

(n) The pharmacy shall keep accurate patient profiles or medication administration records showing all emergency contraception drugs initiated to patients for at least 3 years.

(o) The pharmacist shall obtain written informed consent from the patient and document the informed consent in accordance with the approved protocol for emergency contraception drug therapy. A record of such consent must be maintained by the pharmacy for a period of at least 3 years.

(p) Nothing in this Section may be construed to affect any provision of law relating to the confidentiality of medical records.

(q) Nothing in this Section may be construed as creating a

duty for any pharmacist to enter into a collaborative agreement to initiate emergency contraception drug therapy with an authorized prescriber, nor creating a duty for any authorized prescriber to enter into a collaborative agreement with a pharmacist to initiate emergency contraception drug therapy.

(s) The Department shall adopt rules for the administration of this Section within 60 days after the effective date of this amendatory Act of the 95th General Assembly.

Section 15. The Illinois Food, Drug and Cosmetic Act is amended by changing Section 3.21 as follows:

(410 ILCS 620/3.21) (from Ch. 56 1/2, par. 503.21)

Sec. 3.21. Except as authorized by this Act, the Controlled Substances Act, the Pharmacy Practice Act of 1987, the Dental Practice Act, the Medical Practice Act of 1987, the Veterinary Medicine and Surgery Practice Act of 2004, or the Podiatric Medical Practice Act of 1987, to sell or dispense a prescription drug without a prescription.

Nothing in this Section shall be construed to prohibit a pharmacist from initiating emergency contraception drug therapy in accordance with Section 22b of the Pharmacy Practice Act of 1987.

(Source: P.A. 93-281, eff. 12-31-03.)

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