HB2535

LRB094 06347 RAS 36423 b

94TH GENERAL ASSEMBLY

State of Illinois

2005 and 2006

HB2535

Introduced 2/18/2005, by Rep. Sara Feigenholtz

SYNOPSIS AS INTRODUCED:

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 and the Illinois Food, Drug and Cosmetics Act to allow pharmacists to initiate emergency contraception drug therapy in accordance with guidelines or protocols developed by the pharmacist and an authorized prescriber who is acting within the prescriber's scope of practice. Requires the pharmacist to provide the recipient of the emergency contraception drugs with a standardized fact sheet.

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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 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 a collaborative agreement 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 individual authorized by law in Illinois to prescribe drugs.

"Collaborative practice" 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:

(i) is used after intercourse;

(ii) is an elevated dose of hormones used to prevent pregnancy;

(iii) is approved by the United States Food and Drug Administration; and

(iv) requires a prescription.

"Guidelines" or "protocol" means a written agreement between a pharmacist or group of pharmacists and an authorized prescriber or group of authorized prescribers 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 guidelines or protocols developed by the pharmacist and an authorized prescriber who is acting within the prescriber's scope of practice.

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.

(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 guidelines or protocol. The guidelines or 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 Board of Pharmacy. A copy of the written guidelines or protocol shall be on file with the Board of Pharmacy. The authorized prescriber

who is a party to the guidelines or protocol shall be in active practice, as outlined by the Department of Financial and Professional Regulation, and the prescriptive authority that the authorized prescriber grants to a pharmacist shall be within the scope of the authorized prescriber's current practice.

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

(1) A statement identifying the individual authorized to prescribe emergency contraception and the pharmacist who is a party to the guidelines or protocol.

(2) A statement that the guideline or protocol is limited only 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 authorized prescriber 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 authorized prescriber will review the documentation and records made by the pharmacist at least once every 3 months.

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

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

(g) The guideline or protocol may be terminated upon

written notice by the authorized prescriber or pharmacist. The pharmacist shall notify the Board of Pharmacy in writing within 30 days after a guideline or protocol is terminated.

(h) Any modification to the guideline or protocol must be approved by the Board of Pharmacy as required by this Section for a new guideline or protocol.

(i) The pharmacist must successfully complete a course of training in the subject area of emergency contraception drug therapy provided by:

(1) the Department of Public Health;

(2) the American Council on Pharmaceutical Education (ACPE); or

(3) a similar health authority, community organization, or professional body approved by the Board of Pharmacy.

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

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

(2) identifying 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.

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

(l) 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 Board of Pharmacy 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 Board of Pharmacy shall consult with and solicit input from the Department of Public Health, the American College of Obstetricians and Gynecologists, Planned Parenthood, and other relevant health care or professional organizations. After this consultation and review, the Board of Pharmacy 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.

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

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

(o) Nothing in this Section affects the provisions of law relating to maintaining the confidentiality of medical records.

(p) 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 under this Section.

(q) Nothing in this Act may be construed as creating a duty for any authorized prescriber to enter into a collaborative agreement with a pharmacist to initiate emergency contraception drug therapy under this Section.

Section 10. 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.)