SENATE AMENDED
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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 751 Session of 2001

INTRODUCED BY ALLEN, HARHART, DeWEESE, ARGALL, ARMSTRONG, M. BAKER, BARRAR, CALTAGIRONE, CLARK, CORRIGAN, COY, CRUZ, DALLY, EACHUS, FEESE, FLEAGLE, FORCIER, FRANKEL, GANNON, HALUSKA, HORSEY, KAISER, LEH, McCALL, McILHATTAN, PRESTON, SATHER, STERN, THOMAS, TIGUE, J. WILLIAMS, WILT, WOJNAROSKI, YOUNGBLOOD, SAYLOR AND LAUGHLIN, FEBRUARY 14, 2001

AS AMENDED ON THIRD CONSIDERATION, IN SENATE, JUNE 19, 2002

AN ACT

Amending the act of September 27, 1961 (P.L.1700, No.699), entitled "An act relating to the regulation of the practice of pharmacy, including the sales, use and distribution of drugs and devices at retail; and amending, revising, consolidating and repealing certain laws relating thereto," further providing for definitions; and providing for drug therapy protocol.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2(11) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, amended December 20, 1985 (P.L.433, No.111), is amended and the section is amended by adding clauses to read:

Section 2. Definitions.--As used in this act:

* * *

(11) "Practice of pharmacy" means the [practice of that profession concerned with the art and science of the evaluation of prescription orders and the preparing, compounding and

dispensing of drugs and devices, whether dispensed on the prescription of a medical practitioner or legally dispensed or provided to a consumer, and shall include the proper and safe storage and distribution of drugs, the maintenance of proper records, the participation in drug selection and drug utilization reviews, and the responsibility of relating information as required concerning such drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease:] provision of health care services by a pharmacist, which includes the interpretation, evaluation and implementation of medical orders FOR THE PROVISION OF PHARMACY SERVICES or prescription drug orders; the delivery, dispensing or distribution of prescription drugs; participation in drug and device selection; drug administration; drug regimen review; drug or drug-related research; compounding; proper and safe storage of drugs and devices; managing drug therapy in an institutional setting CONSISTENT WITH THE INSTITUTION'S ASSIGNMENT OF CLINICAL DUTIES; maintaining proper records; patient counseling; and such acts, services, operations or transactions necessary or incident to the provision of these health care services. [Provided, however, That] The "practice of pharmacy" shall not include the operations of a manufacturer or distributor as defined in "The Controlled Substance, Drug, Device and Cosmetic Act."

* * *

(14) "Managing drug therapy" means any of the following processes which shall be performed in an institutional setting only: Adjusting a drug regimen; adjusting drug strength, frequency of administration or route; administration of drugs; and ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy,

consistent with the testing standards of the ~~health care facility~~ INSTITUTION. Managing drug therapy shall be performed pursuant to a written agreement or protocol as set forth in section 9.1 of this act.~~, authorizing the delegation of management of drug therapy from a licensed physician to a pharmacist, in accordance with section 17 of the act of December 20, 1985 (P.L.457, No.112), known as the "Medical Practice Act of 1985," which authorizes a medical doctor to delegate duties to health care practitioners, and section 3 of the act of October 5, 1978 (P.L.1109, No.261), known as the "Osteopathic Medical Practice Act," which authorizes services and acts rendered by allied medical persons under the supervision, direction or control of a licensed physician.~~

(15) "Institution" means a health care facility as defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the "Health Care Facilities Act," which offers CARE AND medical treatment to patients who require food, board and overnight sleeping facilities ~~and care~~.

(16) "Drug administration" means the direct introduction of or the application of a drug into or on the body of a patient by injection, inhalation, ingestion or any other means, and where required by law, shall occur only pursuant to a medical order.

~~(17) "Medical order" means a lawful order by a specifically identified medical practitioner for a specifically identified patient.~~

~~(18)~~ (17) "Physician" means an individual licensed under the laws of this Commonwealth to engage in the practice of medicine and surgery in all its branches within the scope of the act of December 20, 1985 (P.L.457, No.112), known as the "Medical Practice Act of 1985," or in the practice of osteopathic

medicine within the scope of the act of October 5, 1978 (P.L.1109, No.261), known as the "Osteopathic Medical Practice Act."

~~(19)~~ (18) "Protocol" means a written document that describes the nature and scope of the drug therapy management to be carried out by the pharmacist. <—

Section 2. The act is amended by adding sections to read:

Section 9.1. Drug Therapy Protocols.--(a) A pharmacist shall be permitted to enter into a written agreement or protocol with a licensed physician authorizing the ~~delegation of the~~ management of drug therapy in an institutional setting. <—

(b) The licensed physician who is a party to a written agreement or protocol authorizing the ~~delegation of the~~ management of drug therapy shall be in active practice and the ~~delegation~~ WRITTEN AGREEMENT OR PROTOCOL shall be within the scope of the licensed physician's current practice. <— <—

(c) Participation in a written agreement or protocol authorizing the ~~delegation of the~~ management of drug therapy shall be voluntary, and no licensed physician, PHARMACIST OR INSTITUTION shall be required to participate. <— <—

(d) (1) A pharmacist who is a party to a written agreement or protocol authorizing the ~~delegation of the~~ management of drug therapy shall obtain and maintain, to the satisfaction of the board, professional liability insurance coverage in the minimum amount of one million dollars ($1,000,000) PER OCCURRENCE OR CLAIMS MADE. The professional liability insurance coverage shall remain in effect as long as that pharmacist is a party to a written agreement or protocol authorizing the ~~delegation of the~~ management of drug therapy. Failure to maintain insurance coverage as required under this subsection shall be actionable <— <—

under section 5 of this act.

(2) The board shall accept from pharmacists as satisfactory evidence of insurance coverage under this subsection, any and all of the following: self-insurance, personally purchased professional liability insurance, professional liability insurance coverage provided by the pharmacist's employer or any similar type of coverage.

(3) The board shall adopt, by regulation, standards and procedures established by the Insurance Commissioner for self-insurance. In the absence of these standards and procedures, the board, after consultation with the Insurance Commissioner, shall establish standards and procedures by regulation for self-insurance under this subsection.

(e) Within eighteen months of the effective date of this section, the board shall adopt regulations establishing the parameters of written agreements or protocols authorized by this section. Such parameters shall include, but not be limited to, the requirement that written agreements or protocols:

(1) Be in writing.

(2) Require that drug therapy regimens be initiated by a licensed physician for patients referred to a pharmacist for drug therapy.

(3) Provide for notification of the role of the pharmacist by a licensed physician to each referred patient whose drug therapy management may be affected by the agreement.

(4) Be available as follows:

(i) At the practice site of any licensed physician who is a party to the agreement.

(ii) At the practice site of any licensed pharmacist who is a party to the agreement.

(III) AT THE INSTITUTION WHERE A WRITTEN AGREEMENT OR PROTOCOL IS IN PLACE. <—

~~(iii)~~ (IV) To any patient whose drug therapy management is affected by the agreement. <—

~~(iv)~~ (V) Upon request, to ~~investigators~~ REPRESENTATIVES of the State Board of Medicine, the State Board of Osteopathic Medicine ~~and~~, the State Board of Pharmacy AND THE DEPARTMENT OF HEALTH. <—

(5) Identify, by name, each licensed physician and each licensed pharmacist who are parties to the agreement.

(6) Be signed and dated by each licensed physician AND EACH LICENSED PHARMACIST. <—

(7) Specify the functions and tasks which are the subject of the ~~delegation~~ THE WRITTEN AGREEMENT OR PROTOCOL. <—

(8) Provide for execution of the agreement when any licensed physician or licensed pharmacist may be temporarily absent from a practice setting or temporarily unavailable to participate in its execution.

(9) Establish an appropriate time frame, not to exceed seventy-two hours, within which the licensed pharmacist must notify the licensed physician of any changes in dose, duration or frequency of medication prescribed.

(10) Be filed with the State Board of Pharmacy and the State Board of Medicine and/or the State Board of Osteopathic Medicine.

(11) Remain in effect for a period not to exceed two years upon the conclusion of which, or sooner, the parties shall review the agreement and make a determination as to its renewal, necessary modifications or termination.

(12) Allow for termination of the agreement at the request

of any party to it at any time.

(f) Managing drug therapy within an institutional setting may occur without the requirements of subsection (e) provided it is pursuant to a medical order by a licensed physician for managing drug therapy protocol ~~or guideline~~ approved by the medical staff of the institution. <—

Section 9.2. Authority to Administer Injectable Medications, Biologicals and Immunizations.--(a) Within eighteen months from the effective date of this section, the board shall by regulation establish education and training standards and practice guidelines pursuant to which pharmacists shall be authorized to administer injectable medications, biologicals and immunizations to persons who are more than eighteen years of age. Such standards and guidelines shall include, but not be limited to, the following:

(1) Satisfactory completion of an academic and practical curriculum approved by the board that includes the current guidelines and recommendations of the Centers for Disease Control and Prevention in the Public Health Service of the United States Department of Health and Human Services, the American Council on Pharmaceutical Education or a similar health authority or professional body, and includes, but is not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events and related topics.

(2) Maintenance of a current cardiopulmonary resuscitation (CPR) certificate acceptable to the board.

(3) That the administration of injectable medications, biologicals and immunizations be in accordance with a definitive set of treatment guidelines established by a physician and

approved by the board.

(4) That a minimum of two hours of the thirty-hour requirement for continuing education for license renewal be dedicated to this area of practice.

(b) A pharmacist's authority to administer injectable medications, biologicals and immunizations shall not be delegated to any other person.

Section 3. This act shall take effect in 60 days.