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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1041 Session of 2009

INTRODUCED BY KULA, McILVAINE SMITH, MANN, SOLOBAY, BARRAR, BRENNAN, CARROLL, DeLUCA, EVERETT, GEIST, GROVE, HALUSKA, HARHAI, JOSEPHS, KORTZ, LONGIETTI, MUNDY, PASHINSKI, REICHLEY, SIPTROTH, J. TAYLOR, K. SMITH, VULAKOVICH, MAHONEY, HORNAMAN, GIBBONS, FABRIZIO, MURT AND HENNESSEY, MARCH 23, 2009

AS REPORTED FROM COMMITTEE ON PROFESSIONAL LICENSURE, HOUSE OF REPRESENTATIVES, AS AMENDED, MAY 5, 2009

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, for refusal to grant revocation and suspension and for drug therapy protocols; and providing for collaborative drug therapy management and for construction of act.

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

Section 1. Section 2(11) and (14) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, amended or added June 29, 2002 (P.L.673, No.102), are amended to read:

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

* * *

(11) "Practice of pharmacy" means the 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; medication therapy management, including such services provided under the Medicare Prescription Drug, Improvements, and Modernization Act of 2003 (Public Law 108-172, 117 Stat. 2066); drug or drug-related research; compounding; proper and safe storage of drugs and devices; **[**managing**]** MANAGEMENT OF drug therapy pursuant to section 9.3 or, if in an institutional setting, consistent with the institution's assignment of clinical duties pursuant to a written agreement or protocol as set forth in section 9.1; maintaining proper records; patient counseling; and such acts, services, operations or transactions necessary or incident to the provision of these health care services. 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**]** "MANAGEMENT OF drug therapy" means any of the following processes which shall be performed [in an institutional setting only] pursuant to a written agreement or protocol as set forth in section 9.1 or pursuant to section 9.3: 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 institution. **[**Managing**]** THE MANAGEMENT OF drug therapy shall be performed pursuant to a written agreement or protocol as set forth in section 9.1 of

this act.]; monitoring the patient's vital signs; and providing education and training to the patient which is related to the management of drug therapy. ~~Managing~~ THE MANAGEMENT OF drug therapy under section 9.1 shall be performed consistent with the institution's assignment of clinical duties, and ordering of laboratory tests and ordering or performing other diagnostic tests necessary in the management of drug therapy shall be consistent with the testing standards of the institution.

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Section 2. Section 5(a)(9) AND (B) of the act, amended December 20, 1985 (P.L.433, No.111), is amended to read:

Section 5. Refusal to Grant, Revocation and Suspension.--(a) The board shall have the power to refuse, revoke or suspend the license of any pharmacist upon proof satisfactory to it that the pharmacist:

* * *

(9) Is guilty of grossly unprofessional conduct. The following acts on the part of a pharmacist are hereby declared to constitute grossly unprofessional conduct of a pharmacist:

(i) Willfully deceiving or attempting to deceive the State Board of Pharmacy or its agents with respect to any material matter under investigation by the board;

(ii) Advertising of prices for drugs and pharmaceutical services to the public which does not conform to Federal laws or regulations;

(iii) The public assertion or implication of professional superiority in the practice of pharmacy;

(iv) The engaging by any means in untrue, false, misleading or deceptive advertising of drugs or devices;

(v) Paying rebates to physicians or any other persons, or

the entering into any agreement with a medical practitioner or any other person for the payment or acceptance of compensation in any form for the recommending of the professional services of either party;

(vi) The entering into of any agreement with a licensed medical practitioner for the compounding or dispensing of secret formula (coded), prescriptions;

(vii) The misbranding or adulteration of any drug or device and the sale, distribution or dispensing of any misbranded or adulterated drug or device as defined in the act of April 14, 1972 (P.L.233, No.64), known as "The Controlled Substance, Drug, Device and Cosmetic Act";

(viii) Engaging in the sale or purchase of drugs or devices whose package bears the inscription "sample" or "not for resale";

(ix) Displaying or permitting the display of his certificate of licensure and biennial registration document in a pharmacy of which he is not the proprietor or in which he is not employed;

(x) Any holder of a biennial pocket registration card who fails to have the card available for inspection by an authorized agent when he is practicing;

(xi) The acceptance back and redistribution of any unused drug, or a part thereof, after it has left the premises of any pharmacy, whether issued by mistake or otherwise, unless it is in the original sealed container with the name, lot number and expiration date on the original intact manufacturer's label. The pharmacy shall maintain records of all such returns, and a full refund shall be given to the original purchaser, including a third-party payor;

~~(~~(xii) **[**To accept**]** ACCEPTING employment as a pharmacist, or ←

share or receive compensation in any form arising out of, or incidental to, his professional activities from any medical practitioner or any other person or corporation in which one or more medical practitioners have a proprietary or beneficial interest sufficient to permit them to exercise supervision or control over the pharmacist in his professional responsibilities and duties, EXCEPT THAT A PHARMACIST MAY BE EMPLOYED BY A MEDICAL PRACTITIONER FOR THE PURPOSE OF THE MANAGEMENT OF DRUG THERAPY AND RECEIVE APPROPRIATE COMPENSATION FOR SUCH EMPLOYMENT, BUT NOT ENGAGE IN RETAIL DISPENSING WHILE IN HEALTH CARE PRACTICE WITHIN THE CONTEXT OF SUCH EMPLOYMENT;

(xiii) **[**To accept**]** ACCEPTING employment as a pharmacist, or share or receive compensation in any form arising out of, or incidental to, his professional activities from any person who orders said pharmacist, directly or indirectly, to engage in any aspect of the practice of pharmacy in contravention of any provision of this act**[**.**]**

~~(xii) To accept employment as a pharmacist from any health care practitioner, other person or entity, whereby the pharmacist engages in any aspect of the practice of pharmacy in contravention of any provision of this act or Federal law.~~

~~(xiii) To share or receive compensation in any form arising out of, or incidental to, his professional activities whereby the pharmacist engaged in any aspect of the practice of pharmacy in contravention of any provision of this act or Federal law.~~

~~(xiv) It shall be unlawful for a pharmacist or pharmacy permit holder to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom~~

~~of choice to select a pharmacy.~~, EXCEPT THAT A PHARMACIST MAY BE EMPLOYED BY A MEDICAL PRACTITIONER FOR THE PURPOSE OF THE MANAGEMENT OF DRUG THERAPY AND RECEIVE APPROPRIATE COMPENSATION FOR SUCH EMPLOYMENT, BUT NOT ENGAGE IN RETAIL DISPENSING WHILE IN THE HEALTH CARE PRACTICE WITHIN THE CONTEXT OF SUCH EMPLOYMENT;

(XIV) ENTERING INTO AN ARRANGEMENT WITH A MEDICAL PRACTITIONER WHO IS LICENSED TO ISSUE PRESCRIPTIONS FOR THE PURPOSE OF DIRECTING OR DIVERTING PATIENTS TO OR FROM A SPECIFIED PHARMACY OR RESTRAINING A PATIENT'S FREEDOM OF CHOICE TO SELECT A PHARMACY, EXCEPT THAT THIS SHALL NOT BE CONSTRUED TO PROHIBIT A PHARMACIST FROM ENTERING INTO A WRITTEN AGREEMENT OR WRITTEN COLLABORATIVE AGREEMENT WITH A LICENSED PHYSICIAN WHICH AUTHORIZES THE MANAGEMENT OF DRUG THERAPY.

(B) THE BOARD SHALL HAVE THE POWER TO REFUSE, REVOKE OR SUSPEND THE PERMIT OF ANY PHARMACY UPON PROOF SATISFACTORY TO IT THAT:

(1) THE PERMIT WAS PROCURED THROUGH FRAUD, MISREPRESENTATION OR DECEIT;

(2) THE HOLDER OR PARTNER OR OFFICER THEREOF HAS VIOLATED ANY OF THE PROVISIONS OF THIS ACT OR REGULATIONS OF THE BOARD APPLICABLE TO HIM OR ANY PROVISION OF "THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT" OR THE FEDERAL ACT, OR HAS ORDERED A PHARMACIST IN HIS EMPLOY TO ENGAGE IN ANY ASPECT OF THE PRACTICE OF PHARMACY IN CONTRAVENTION OF ANY PROVISIONS OF THE AFORESAID ACTS OR REGULATIONS THEREUNDER;

(3) THE HOLDER THEREOF SOLD, DISPENSED OR CAUSED OR ALLOWED TO BE SOLD OR DISPENSED ANY CONTROLLED SUBSTANCE OR NON-PROPRIETARY DRUG, EXCEPT BY A LICENSED PHARMACIST;

(4) THE HOLDER THEREOF, AFTER ISSUANCE OF A PERMIT, FAILS TO

CONTINUE TO COMPLY WITH ALL REQUIREMENTS OF SECTION 4 HEREOF;

(5) UPON THE SUSPENSION OR REVOCATION OF A LICENSE OF A PHARMACIST EMPLOYED BY SAID INDIVIDUAL, IT IS SHOWN THAT THE ILLEGAL ACTS OF THE PHARMACIST WERE WITHIN THE KNOWLEDGE OR SHOULD HAVE BEEN WITHIN THE KNOWLEDGE OF THE PERMIT HOLDER, PARTNER OR OFFICER[.];

(6) A PHARMACIST OR PHARMACY PERMIT HOLDER ENTERED INTO AN AGREEMENT WITH A MEDICAL PRACTITIONER WHO IS LICENSED TO ISSUE PRESCRIPTIONS FOR THE PURPOSE OF DIRECTING OR DIVERTING PATIENTS TO OR FROM A SPECIFIED PHARMACY OR RESTRAINING IN ANY WAY A PATIENT'S FREEDOM OF CHOICE TO SELECT A PHARMACY.

* * *

Section 3. Section ~~9.1(e) introductory paragraph~~ 9.1(D)(2) AND (3), added June 29, 2002 (P.L.673, No.102), ~~is amended and the subsection is amended by adding a clause~~ ARE AMENDED to read:

Section 9.1. Drug Therapy Protocols.--* * *

~~(e) [Within eighteen months of the effective date of this section, the]~~ 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:~~

~~* * *~~

~~(13) Require a licensed pharmacist to provide to the board satisfactory evidence of completion of all necessary training required in the management of drug therapy for a disease , or for a condition or symptom of a disease, which is the subject of the written agreement or protocol. A licensed pharmacist practicing the management of drug therapy in an institutional setting on the effective date of this clause shall not be~~

~~required to comply with the training requirement specified in this clause.~~

(D) * * *

(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.]

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Section 4. The act is amended by adding sections to read:

Section 9.3. Collaborative Drug Therapy Management.--(a) A ~~licensed~~ pharmacist shall ~~be permitted to~~ enter into a WRITTEN collaborative agreement with a licensed physician authorizing the management of drug therapy for a disease, or for a condition or symptom of a disease, BEFORE PRACTICING THE MANAGEMENT OF DRUG THERAPY in a setting other than an institutional setting.

(b) A ~~licensed~~ pharmacist who is a party to a collaborative agreement authorizing the management of drug therapy must comply with the following:

(1) ~~Be able to provide~~ PROVIDE to the board satisfactory evidence of training in the management of drug therapy for a disease, or for a condition or symptom of a disease, which is the subject of the collaborative agreement. ~~A licensed~~

~~pharmacist practicing the management of drug therapy in an institutional setting on the effective date of this section shall not be required to comply with this clause.~~

~~(2) Complies with registration by the board. A list of registrants shall be accessible by the public.~~

~~(3) Of the continuing education credits completed as a condition of biennial renewal, has two continuing education credits that focus on the management of drug therapy or focus on a disease, or on a condition or symptom of a disease, being treated through drug therapy.~~

~~(4) Must utilize an area for consultation~~

(2) UTILIZE AN AREA FOR IN PERSON, TELEPHONIC OR OTHER APPROVED ELECTRONIC CONSULTATIONS relating to the management of drug therapy that ensures the confidentiality of the patient information being discussed.

(c) (1) ~~(i)~~ A pharmacist who is a party to a collaborative agreement authorizing the management of drug therapy shall obtain and maintain~~, to the satisfaction of the board,~~ A LEVEL OF 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 management of drug therapy.~~

~~(ii) Failure to maintain insurance coverage as required under this subsection shall be actionable under section 5.~~

~~(2) The board shall accept from a pharmacist 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.~~ FAILURE TO MAINTAIN INSURANCE COVERAGE AS REQUIRED SHALL SUBJECT THE LICENSEE TO DISCIPLINARY PROCEEDINGS. THE BOARD SHALL ACCEPT FROM A LICENSEE AS SATISFACTORY EVIDENCE OF INSURANCE COVERAGE ANY OF THE FOLLOWING:

(I) PERSONAL PURCHASED LIABILITY INSURANCE;

(II) PROFESSIONAL LIABILITY INSURANCE COVERAGE PROVIDED BY THE INDIVIDUAL LICENSEE'S EMPLOYER; OR

(III) SIMILAR INSURANCE COVERAGE ACCEPTABLE TO THE BOARD.

(2) A LICENSEE PRACTICING UNDER THIS SECTION SHALL PROVIDE PROOF TO THE BOARD THAT THE LICENSEE HAS OBTAINED PROFESSIONAL LIABILITY INSURANCE IN ACCORDANCE WITH THIS SUBSECTION. IT IS SUFFICIENT IF THE LICENSEE FILES WITH THE COLLABORATIVE AGREEMENT A COPY OF A LETTER FROM THE LICENSEE'S PROFESSIONAL LIABILITY INSURANCE CARRIER INDICATING THE LICENSEE WILL BE COVERED AGAINST PROFESSIONAL LIABILITY IN THE REQUIRED AMOUNTS PRIOR TO THE LICENSEE'S PRACTICE UNDER THIS SECTION.

(d) A ~~licensed~~ pharmacist may not provide economic incentives to a licensed physician for the purpose of entering into a collaborative agreement for the management of drug therapy.

(e) The management of drug therapy pursuant to a collaborative agreement shall be initiated by a written referral

from the LICENSED physician to the pharmacist. The written referral shall include the frequency in which the pharmacist must conduct the management of drug therapy in person.

(f) The licensed physician who is a party to the collaborative agreement authorizing the management of drug therapy shall ~~be in active practice and in good standing, and~~ HOLD AN ACTIVE LICENSE IN GOOD STANDING AND IN ACCORDANCE WITH THE TERMS OF the collaborative agreement shall be within the scope of the licensed physician's current practice.

(g) Participation in a collaborative agreement authorizing the management of drug therapy shall be voluntary, and no licensed physician or pharmacist shall be required to participate.

(h) A patient's records related to the management of drug therapy may be maintained in ~~an automated system~~ A COMPUTERIZED RECORDKEEPING SYSTEM WHICH MEETS ALL REQUIREMENTS FOR FEDERAL AND STATE-CERTIFIED ELECTRONIC HEALTH CARE RECORDS.

(i) A ~~licensed~~ pharmacist who is a party to the collaborative agreement authorizing the management of drug therapy shall have access to the records of ~~a~~ THE patient who is the recipient of the management of drug therapy.

(j) ~~All patient records in the possession of a licensed~~ THE HANDLING OF ALL PATIENT RECORDS BY THE pharmacist providing the management of drug therapy must comply with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936).

(k) The collaborative agreement must:

(1) Be between a licensed physician and a ~~licensed~~ pharmacist.

(2) Comply with the requirements specified in section

9.1(e).

(3) Specify the terms under which a ~~licensed~~ pharmacist providing THE MANAGEMENT OF drug therapy ~~services~~ is permitted to adjust drug regimen or to adjust drug strength, frequency of administration or route without prior written or oral consent by the collaborating physician.

Section 9.4. Construction.--Nothing in this act shall be construed to provide prescriptive authority to a ~~licensed~~ pharmacist.

Section 5. The State Board of Pharmacy shall promulgate regulations to implement the addition of section 9.3 of the act within 18 months of the effective date of this section. ~~The addition of section 9.3 of the act shall not be enforceable by the State Board of Pharmacy until the publication of final regulations.~~

Section 6. This act shall take effect ~~in 60 days.~~ AS FOLLOWS:

(1) THE ADDITION OF SECTION 9.3 OF THE ACT SHALL TAKE EFFECT ON THE EARLIER OF:

(I) THE EFFECTIVE DATE OF THE REGULATIONS PROMULGATED UNDER SECTION 5 OF THIS ACT; OR

(II) 24 MONTHS FOLLOWING ENACTMENT OF THIS ACT.

(2) THE REMAINDER OF THIS ACT SHALL TAKE EFFECT IN 60 DAYS.