

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, HENNESSEY AND CALTAGIRONE,
MARCH 23, 2009

SENATOR CORMAN, APPROPRIATIONS, IN SENATE, RE-REPORTED AS
AMENDED, APRIL 19, 2010

AN ACT

1 Amending the act of September 27, 1961 (P.L.1700, No.699),
2 entitled "An act relating to the regulation of the practice
3 of pharmacy, including the sales, use and distribution of
4 drugs and devices at retail; and amending, revising,
5 consolidating and repealing certain laws relating thereto,"
6 further providing for definitions, for refusal to grant
7 revocation and suspension and for drug therapy protocols; and
8 providing for collaborative drug therapy management and for
9 construction of act.

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

12 Section 1. Section 2(11) and (14) of the act of September
13 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, amended
14 or added June 29, 2002 (P.L.673, No.102), are amended to read:

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

16 * * *

17 (11) "Practice of pharmacy" means the provision of health
18 care services by a pharmacist, which includes the

1 interpretation, evaluation and implementation of medical orders
2 for the provision of pharmacy services or prescription drug
3 orders; the delivery, dispensing or distribution of prescription
4 drugs; participation in drug and device selection; drug
5 administration; drug regimen review; ~~medication~~ DRUG therapy
6 management, including such services provided under the Medicare
7 Prescription Drug, Improvements, and Modernization Act of 2003
8 (Public Law 108-172, 117 Stat. 2066); drug or drug-related
9 research; compounding; proper and safe storage of drugs and
10 devices; [managing] management of drug therapy pursuant to
11 section 9.3 or, if in an institutional setting, consistent with
12 the institution's assignment of clinical duties pursuant to a
13 written agreement or protocol as set forth in section 9.1;
14 maintaining proper records; patient counseling; and such acts,
15 services, operations or transactions necessary or incident to
16 the provision of these health care services. The "practice of
17 pharmacy" shall not include the operations of a manufacturer or
18 distributor as defined in "The Controlled Substance, Drug,
19 Device and Cosmetic Act."

20 * * *

21 (14) ["Managing] "Management of drug therapy" means any of
22 the following processes which shall be performed [in an
23 institutional setting only] pursuant to a written agreement or
24 protocol as set forth in section 9.1 or pursuant to section 9.3:
25 adjusting a drug regimen; adjusting drug strength, frequency of
26 administration or route; administration of drugs; [and] ordering
27 laboratory tests and ordering and performing other diagnostic
28 tests necessary in the management of drug therapy[, consistent
29 with the testing standards of the institution. [Managing] The
30 management of drug therapy shall be performed pursuant to a

1 written agreement or protocol as set forth in section 9.1 of
2 this act.]; monitoring the patient's vital signs; and providing
3 education and training to the patient which is related to the
4 management of drug therapy. The management of drug therapy under
5 section 9.1 shall be performed consistent with the institution's
6 assignment of clinical duties, and ordering of laboratory tests
7 and ordering or performing other diagnostic tests necessary in
8 the management of drug therapy shall be consistent with the
9 testing standards of the institution.

10 * * *

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

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

17 * * *

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

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

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

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

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

1 (v) Paying rebates to physicians or any other persons, or
2 the entering into any agreement with a medical practitioner or
3 any other person for the payment or acceptance of compensation
4 in any form for the recommending of the professional services of
5 either party;

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

9 (vii) The misbranding or adulteration of any drug or device
10 and the sale, distribution or dispensing of any misbranded or
11 adulterated drug or device as defined in the act of April 14,
12 1972 (P.L.233, No.64), known as "The Controlled Substance, Drug,
13 Device and Cosmetic Act";

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

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

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

23 (xi) The acceptance back and redistribution of any unused
24 drug, or a part thereof, after it has left the premises of any
25 pharmacy, whether issued by mistake or otherwise, unless it is
26 in the original sealed container with the name, lot number and
27 expiration date on the original intact manufacturer's label. The
28 pharmacy shall maintain records of all such returns, and a full
29 refund shall be given to the original purchaser, including a
30 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~~ PHYSICIAN 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[.], except that a pharmacist may be employed by a ~~medical practitioner~~ PHYSICIAN 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

1 authorizes the management of drug therapy.

2 (b) The board shall have the power to refuse, revoke or
3 suspend the permit of any pharmacy upon proof satisfactory to it
4 that:

5 (1) The permit was procured through fraud, misrepresentation
6 or deceit;

7 (2) The holder or partner or officer thereof has violated
8 any of the provisions of this act or regulations of the board
9 applicable to him or any provision of "The Controlled Substance,
10 Drug, Device and Cosmetic Act" or the Federal act, or has
11 ordered a pharmacist in his employ to engage in any aspect of
12 the practice of pharmacy in contravention of any provisions of
13 the aforesaid acts or regulations thereunder;

14 (3) The holder thereof sold, dispensed or caused or allowed
15 to be sold or dispensed any controlled substance or non-
16 proprietary drug, except by a licensed pharmacist;

17 (4) The holder thereof, after issuance of a permit, fails to
18 continue to comply with all requirements of section 4 hereof;

19 (5) Upon the suspension or revocation of a license of a
20 pharmacist employed by said individual, it is shown that the
21 illegal acts of the pharmacist were within the knowledge or
22 should have been within the knowledge of the permit holder,
23 partner or officer[.];

24 (6) A pharmacist or pharmacy permit holder entered into an
25 agreement with a medical practitioner who is licensed to issue
26 prescriptions for the purpose of directing or diverting patients
27 to or from a specified pharmacy or restraining in any way a
28 patient's freedom of choice to select a pharmacy.

29 * * *

30 Section 3. Section 9.1(d) (2) and (3), added June 29, 2002

1 (P.L.673, No.102), are amended to read:

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

3 (d) * * *

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

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

16 * * *

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

18 Section 9.3. Collaborative Drug Therapy Management.--(a) A
19 pharmacist shall enter into a written collaborative agreement
20 with a licensed physician authorizing the management of drug
21 therapy for a disease, or for a condition or symptom of a
22 disease, before practicing the management of drug therapy in a
23 setting other than an institutional setting.

24 (b) A pharmacist who is a party to a collaborative agreement
25 authorizing the management of drug therapy must comply with the ←
26 following:

27 (1) Provide to the board satisfactory evidence of training
28 in the management of drug therapy for a disease, or for a
29 condition or symptom of a disease, which is the subject of the
30 collaborative agreement. SHALL ←

~~(2) Utilize~~ 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) A pharmacist who is a party to a collaborative agreement authorizing the management of drug therapy shall obtain and maintain a level of professional liability insurance coverage in the minimum amount of one million dollars (\$1,000,000) per occurrence or claims made. 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~~ AN AFFIDAVIT 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 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

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

4 (f) The licensed physician who is a party to the
5 collaborative agreement authorizing the management of drug
6 therapy shall hold an active license in good standing and in
7 accordance with the terms of the collaborative agreement shall
8 be within the scope of the licensed physician's current
9 practice.

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

14 (h) A patient's records related to the management of drug
15 therapy may be maintained in a computerized recordkeeping system
16 which meets all requirements for Federal and State-certified
17 electronic health care records.

18 (i) A pharmacist who is a party to the collaborative
19 agreement authorizing the management of drug therapy shall have
20 access to the records of the patient who is the recipient of the
21 management of drug therapy.

22 (j) The handling of all patient records by the pharmacist
23 providing the management of drug therapy must comply with the
24 Health Insurance Portability and Accountability Act of 1996
25 (Public Law 104-191, 110 Stat. 1936).

26 (k) The collaborative agreement must:

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

28 (2) Comply with the requirements specified in section
29 9.1(e).

30 (3) Specify the terms under which a pharmacist providing the

1 management of drug therapy is permitted to adjust drug regimen
2 or to adjust drug strength, frequency of administration or route
3 without prior written or oral consent by the collaborating
4 physician.

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

7 Section 5. The State Board of Pharmacy shall promulgate
8 regulations to implement the addition of section 9.3 of the act
9 within 18 months of the effective date of this section.

10 Section 6. This act shall take effect as follows:

11 (1) The addition of section 9.3 of the act shall take
12 effect on the earlier of:

13 (i) the effective date of the regulations
14 promulgated under section 5 of this act; or

15 (ii) 24 months following enactment of this act.

16 (2) The remainder of this act shall take effect in 60
17 days.