

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL**No. 1250** Session of
2007

INTRODUCED BY KULA, EACHUS, KORTZ, SOLOBAY, MAHONEY, JOSEPHS,
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PASHINSKI AND CALTAGIRONE, MAY 8, 2007

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES,
NOVEMBER 20, 2007

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; providing for registration
7 and permits for pharmacy technicians; further providing for
8 multiple licensure, for refusal to grant revocation and
9 suspension, for State Board of Pharmacy, for hearings and
10 suspensions, for reinstatement, for drug therapy protocols
11 and for penalties; and providing for collaborative drug
12 therapy management.

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

15 Section 1. Section 2(11) and (14) of the act of September
16 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act, amended
17 or added June 29, 2002 (P.L.673, No.102), are amended and the
18 section is amended by adding paragraphs to read:

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

20 * * *

21 (10.1) "Pharmacy technician" means an individual who is

1 registered by the State Board of Pharmacy under section 2.1 to
2 assist in the practice of pharmacy.

3 (10.2) "Pharmacy technician trainee" means an individual who
4 holds a temporary permit issued by the State Board of Pharmacy
5 under section 2.1.

6 (10.3) "Direct and personal supervision of a pharmacist"
7 means:

8 (i) review by the pharmacist of the prescription or drug
9 order prior to dispensing;

10 (ii) verification by the pharmacist of the final product;
11 and

12 (iii) the pharmacist's availability on the premises to
13 direct the work of the supervised individual and to respond to
14 questions or problems.

15 (11) "Practice of pharmacy" means the provision of health
16 care services by a pharmacist, which includes the
17 interpretation, evaluation and implementation of medical orders
18 for the provision of pharmacy services or prescription drug
19 orders; the delivery, dispensing or distribution of prescription
20 drugs; participation in drug and device selection; drug
21 administration; drug regimen review; medication therapy
22 management, including such services provided under the Medicare
23 Prescription Drug Improvement and Modernization Act of 2003;
24 drug or drug-related research; compounding; proper and safe
25 storage of drugs and devices; managing drug therapy pursuant to
26 section 9.3 or, if in an institutional setting, consistent with
27 the institution's assignment of clinical duties pursuant to a
28 written agreement ~~of~~ OR protocol as set forth in section 9.1; <—

29 maintaining proper records; patient counseling; and such acts,
30 services, operations or transactions necessary or incident to

1 the provision of these health care services. The "practice of
2 pharmacy" shall not include the operations of a manufacturer or
3 distributor as defined in "The Controlled Substance, Drug,
4 Device and Cosmetic Act."

5 * * *

6 (14) "Managing drug therapy" means any of the following
7 processes which shall be performed [in an institutional setting
8 only] pursuant to a written agreement or protocol as set forth
9 in section 9.1 or pursuant to section 9.3: adjusting a drug
10 regimen; adjusting drug strength, frequency of administration or
11 route; administration of drugs; [and] ordering laboratory tests
12 and ordering and performing other diagnostic tests necessary in
13 the management of drug therapy[, consistent with the testing
14 standards of the institution. Managing drug therapy shall be
15 performed pursuant to a written agreement or protocol as set
16 forth in section 9.1 of this act.]; monitoring the patient's
17 vital signs; and providing education and training to the patient
18 which is related to the management of drug therapy. Managing
19 drug therapy under section 9.1 shall be performed consistent
20 with the institution's assignment of clinical duties and
21 ordering of laboratory tests and ordering or performing other
22 diagnostic tests necessary in the management of drug therapy
23 shall be consistent with the testing standards of the
24 institution.

25 * * *

26 Section 2. The act is amended by adding a section to read:

27 Section 2.1. Registration and Permits for Pharmacy
28 Technicians.--(a) The board may register as a pharmacy
29 technician any individual who does the following:

30 (1) Pays an application fee prescribed by the department.

1 (2) Files an application for registration, subscribed by the
2 individual under oath or affirmation, containing information the
3 board requires.

4 (3) Except as set forth in subsection (b), complies with all
5 of the following:

6 (i) Is not less than eighteen years of age and is a legal
7 resident of the United States.

8 (ii) Has a high school diploma or its equivalent.

9 (iii) Has satisfied the board that the applicant is of good
10 moral character and is not unfit or unable to practice as a
11 pharmacy technician by reason of the extent or manner of his use
12 of alcoholic beverages or controlled substances or by reason of
13 a physical or mental disability.

14 (iv) Has completed a pharmacy technician training program
15 approved by the board.

16 ~~(v) Has received certification from a nationally recognized~~ <—
17 ~~certifying agency approved by the board.~~

18 ~~(vi) Has successfully completed an examination approved by~~
19 ~~the board.~~

20 ~~(vii) Examinations shall be administered in accordance~~

21 (V) HAS: <—

22 (A) RECEIVED CERTIFICATION FROM A NATIONALLY RECOGNIZED
23 CERTIFYING AGENCY APPROVED BY THE BOARD; OR

24 (B) SUCCESSFULLY COMPLETED AN EXAMINATION APPROVED BY THE
25 BOARD AND ADMINISTERED IN ACCORDANCE with the requirements set
26 forth in section 812.1(a) of the act of April 9, 1929 (P.L.177,
27 No.175), known as "The Administrative Code of 1929."

28 ~~(viii) (VI) Has not been convicted of a felonious act~~ <—
29 ~~prohibited by the act of April 14, 1972 (P.L.233, No.64), known~~
30 ~~as "The Controlled Substance, Drug, Device and Cosmetic Act," or~~

1 convicted of a felony relating to a controlled substance in a
2 court of law of the United States or any other state, territory
3 or country unless:

4 (A) at least ten years have elapsed from the date of
5 conviction; and

6 (B) the applicant satisfactorily demonstrates to the board
7 that the applicant has made significant progress in personal
8 rehabilitation since the conviction such that licensure of the
9 applicant should not be expected to create a substantial risk of
10 harm to the health and safety of patients or the public or a
11 substantial risk of further criminal violations. As used in this
12 clause, the term "convicted" shall include a judgment, an
13 admission of guilt or a plea of nolo contendere. An applicant's
14 statement on the application declaring the absence of a
15 conviction shall be deemed satisfactory evidence of the absence
16 of a conviction, unless the board has some evidence to the
17 contrary.

18 (b) The following apply:

19 (1) Notwithstanding subsection (a)(3)(iv) and (v), the board
20 shall register all of the following:

21 (i) An individual who, at the time of filing an application,
22 has proof ~~of~~ OF registration, certification or licensure or its ←
23 equivalent as a pharmacy technician in another state, territory
24 or possession of the United States which has registration,
25 certification, licensure or equivalent requirements comparable
26 to those set forth in this section and regulations of the board.

27 (ii) An individual who:

28 (A) applies for registration within two years after the
29 effective date of this section; and

30 (B) on the effective date of this section maintains a

1 current certification by a nationally recognized pharmacy
2 technician association.

3 (2) Notwithstanding subsection (a)(3)(ii), (iv) and (v), the
4 board shall issue registration to an individual who:

5 (i) Has been employed as a pharmacy technician for a minimum
6 of ~~2,000~~ TWO THOUSAND hours during the three years immediately ←
7 preceding the enactment of this act.

8 (ii) Demonstrates to the satisfaction of the board proof of
9 practice as a pharmacy technician for at least two thousand
10 hours immediately prior to the date of application.

11 (c) A registration shall authorize the registrant to assist
12 in the practice of pharmacy under the direct and personal
13 supervision of a pharmacist.

14 (d) A registration is subject to biennial renewal. The board
15 shall establish a fee for renewal by regulation.

16 (e) The following apply to pharmacy technician trainees:

17 (1) The board shall MAY issue a temporary permit to practice ←
18 as a pharmacy technician trainee to an applicant who is
19 seventeen years of age or older and meets the requirements of
20 subsection (a)(3)(ii) and (iii) and complies with the following:

21 (i) The individual is a student enrolled in a board-approved
22 pharmacy technician training program and as part of the program
23 may be required to serve an externship or internship; or

24 (ii) The individual is employed by a pharmacy and
25 participates in a board-approved pharmacy technician training
26 program which may include an externship or internship program.

27 (2) A temporary practice permit shall be issued for one year
28 and may be extended for a single six-month period upon
29 verification to the satisfaction of the board that the trainee
30 has completed the board-approved training program.

1 (3) A temporary permit shall not be reissued.

2 (4) A temporary permit shall authorize the permittee to
3 perform the duties of a pharmacy technician under the direct and
4 personal supervision of a pharmacist.

5 (f) Identification requirements are as follows:

6 (1) A pharmacy technician shall wear a name tag that clearly
7 identifies the pharmacy technician with the title "~~licensed~~ <—
8 "REGISTERED pharmacy technician." <—

9 (2) A holder of a temporary permit shall wear a name tag
10 that clearly identifies the temporary permit holder with the
11 title "~~registered pharmacy~~ "PHARMACY technician trainee." <—

12 (g) This section shall not apply to any student who is
13 enrolled in an accredited school of pharmacy and who is in good
14 standing.

15 Section 3. Section 3.2 of the act, added December 20, 1985
16 (P.L.433, No.111), is amended to read:

17 Section 3.2. Reporting of Multiple Licensure, registration
18 or its equivalent.--Any [licensed] pharmacist or pharmacy
19 technician of this Commonwealth who is also registered,
20 certified or licensed [to practice pharmacy] in any other state,
21 territory or country shall report this information to the board
22 on the biennial registration application. Any disciplinary
23 action taken in other states, territories and countries shall be
24 reported to the board on the biennial registration application
25 or within ninety days of final disposition, whichever is sooner.
26 Multiple [licensure] registration, certification or licensure <—
27 shall be noted by the board on the [pharmacist's] licensee's or
28 registrant's record, and such state, territory or country shall
29 be notified by the board of any disciplinary actions taken
30 against [said pharmacist] that licensee or registrant in this

1 Commonwealth.

2 Section 4. Section 5(a)(9) and (c) of the act, amended
3 December 20, 1985 (P.L.433, No.111), are amended and the section
4 is amended by adding a subsection to read:

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

9 * * *

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

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

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

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

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

23 (v) Paying rebates to physicians or any other persons, or
24 the entering into any agreement with a medical practitioner or
25 any other person for the payment or acceptance of compensation
26 in any form for the recommending of the professional services of
27 either party;

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

1 (vii) The misbranding or adulteration of any drug or device
2 and the sale, distribution or dispensing of any misbranded or
3 adulterated drug or device as defined in the act of April 14,
4 1972 (P.L.233, No.64), known as "The Controlled Substance, Drug,
5 Device and Cosmetic Act";

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

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

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

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

23 [(xii) To accept employment as a pharmacist, or share or
24 receive compensation in any form arising out of, or incidental
25 to, his professional activities from any medical practitioner or
26 any other person or corporation in which one or more medical
27 practitioners have a proprietary or beneficial interest
28 sufficient to permit them to exercise supervision or control
29 over the pharmacist in his professional responsibilities and
30 duties;

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

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

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

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

21 (a.1) The board shall have the power to refuse, revoke or
22 suspend the registration of any pharmacy technician upon proof
23 satisfactory to it that the pharmacy technician has done any of
24 the following:

25 (1) Procured a ~~person~~ PERSONAL registration through fraud, ←
26 misrepresentation or deceit.

27 (2) Has been found guilty, pleaded guilty, entered a plea of
28 nolo contendere, or has received probation without verdict,
29 disposition in lieu of trial or an Accelerated Rehabilitative
30 Disposition in the disposition of felony charges, to any offense

1 in connection with the practice of pharmacy or any offense
2 involving moral turpitude before any court of record of any
3 jurisdiction.

4 (3) Is unfit to practice as a pharmacy technician because of
5 intemperance in the use of alcoholic beverages, controlled
6 substances or any other substance which impairs the intellect
7 and judgment to such an extent as to impair the performance of
8 professional duties.

9 (4) Is unfit or unable to practice as a pharmacy technician
10 by reason of a physical or mental disease or disability. In
11 enforcing this clause, the board shall, upon probable cause,
12 have authority to compel a pharmacy technician to submit to a
13 mental or physical examination by physicians or psychologists
14 approved by the board. Failure of a pharmacy technician to
15 submit to examination when directed by the board, unless due to
16 circumstances beyond the pharmacy technician's control, shall
17 constitute an admission of the allegations against the pharmacy
18 technician, consequent upon which a default and final order may
19 be entered without the taking of testimony or presentation of
20 evidence. A pharmacy technician affected under this clause shall
21 at reasonable intervals be afforded an opportunity to
22 demonstrate ~~that~~ THE ability to resume a competent practice as a ←
23 pharmacy technician with reasonable skill and safety to
24 patients.

25 (5) Has had a registration, certification or license to
26 practice as a pharmacy technician denied, revoked or suspended
27 by an appropriate pharmacy technician registration,
28 certification or licensing authority or has received
29 disciplinary action from an appropriate pharmacy technician
30 registration, certification or licensing authority.

1 (6) Has acted in such a manner as to present an immediate
2 and clear danger to the public health or safety.

3 (7) Is guilty of incompetence, gross negligence or other
4 malpractice, or the departure from, or failure to conform to,
5 the standards of acceptable and prevailing pharmacy technician
6 practice, in which case actual injury need not be established.

7 * * *

8 (c) When the board finds that the registration,
9 certification or license [of any pharmacist] may be refused,
10 revoked or suspended under the terms of subsection (a) or (a.1),
11 the board may:

12 (1) Deny the application for a registration, certification
13 or license.

14 (2) Administer a public reprimand.

15 (3) Revoke, suspend, limit or otherwise restrict a
16 registration, certification or license as determined by the
17 board.

18 (4) Require a licensee to submit to the care, counseling or
19 treatment of a physician or a psychologist designated by the
20 board. This clause does not apply to a pharmacy technician.

21 (5) Suspend enforcement of its finding thereof and place a
22 licensee on probation with the right to vacate the probationary
23 order for noncompliance.

24 (6) Restore or reissue, in its discretion, a suspended
25 license [to practice pharmacy] or registration and impose any
26 disciplinary or corrective measure which it might originally
27 have imposed.

28 * * *

29 Section 5. Section 6(k) of the act, amended December 20,
30 1985 (P.L.433, No.111), is amended to read:

1 Section 6. State Board of Pharmacy.--* * *

2 (k) The board shall have the power, and it shall be its
3 duty:

4 (1) To regulate the practice of pharmacy and of pharmacy
5 technicians;

6 (2) To determine the nature of examinations for all
7 applicants for [pharmacists'] licenses;

8 (3) To examine, inspect and investigate all applications and
9 all applicants for licensure as pharmacists, pharmacies or
10 registration as pharmacy interns and pharmacy technicians, and
11 to grant certificates of licensure or registration to all
12 applicants whom it shall judge to be properly qualified;

13 (4) With the approval of the Commissioner of Professional
14 and Occupational Affairs, to prepare position descriptions,
15 employ inspectors who shall be licensed pharmacists or
16 registered pharmacy technicians supervised by licensed <—
17 pharmacists ONE LICENSED PHARMACIST and employ appropriate <—
18 consultants to assist it for any purposes which it may deem
19 necessary, provided that the board may not delegate any of its
20 final decisionmaking responsibilities to any consultant;

21 (4.1) To require that a pharmacy technician hired for
22 purposes of inspecting licensed pharmacies is BE hired with <—
23 consultation of the board and that the pharmacy technician:

24 (i) Has been employed full time as a pharmacy technician in
25 a licensed pharmacy located in this Commonwealth for the
26 immediate prior five years.

27 (ii) Has successfully completed a board of pharmacy
28 inspector training program and examination demonstrating
29 required knowledge of State pharmacy law and regulations.

30 (iii) Reports directly to a supervisor who is a pharmacist

1 licensed in this State that also serves as an inspector
2 performing tasks and duties associated with that responsibility.

3 (5) To investigate or cause to be investigated all
4 violations of the provisions of this act and its regulations and
5 to cause prosecutions to be instituted in the courts upon advice
6 from the Attorney General;

7 (6) To make or order inspections of all pharmacies, except
8 health care facilities, as defined in the act of July 19, 1979
9 (P.L.130, No.48), known as the "Health Care Facilities Act," and
10 which are periodically inspected by the Department of Health in
11 accordance with the standards in this act and the board's
12 regulations promulgated thereto: Provided, That the Department
13 of Health shall forward a copy of their inspection report to the
14 board noting any violations of the act: And, provided further,
15 That, if a violation is reported, the board shall have the power
16 to inspect such pharmacies and take appropriate action as
17 specified in this act; and to make or order inspections of other
18 places in which drugs or devices are stored, held, compounded,
19 dispensed or sold to a consumer, to take and analyze any drugs
20 or devices and to seize and condemn any drugs or devices which
21 are adulterated, misbranded or stored, held, dispensed,
22 distributed or compounded in violation of the provisions of this
23 act or the provisions of the act of April 14, 1972 (P.L.233,
24 No.64), known as "The Controlled Substance, Drug, Device and
25 Cosmetic Act";

26 (7) To conduct hearings for the revocation or suspension of
27 licenses, permits or registrations, for which hearings the board
28 shall have the power to subpoena witnesses;

29 (8) To assist the regularly constituted enforcement agencies
30 of this Commonwealth in enforcing all laws pertaining to drugs,

1 controlled substances, and practice of pharmacy;

2 (8.1) To approve programs for the training of pharmacy
3 technicians;

←

4 (9) To promulgate rules and regulations to effectuate the
5 purposes of this act and to regulate the distribution of drugs
6 and devices and the practice of pharmacy for the protection and
7 promotion of the public health, safety and welfare.

8 * * *

9 Section 6. Section 7 of the act is amended by adding a
10 subsection to read:

11 Section 7. Hearings and Suspensions.--* * *

12 (e) Notwithstanding any other provision, subsections (d.3),
13 (d.4), (d.5), (d.6), (d.7) and (d.8) shall not apply to pharmacy
14 technicians, except as those subsections relate to the
15 professional health monitoring program.

16 Section 7. Sections 7.1, 8(2) and (8) and 8.1 of the act,
17 amended or added December 20, 1985 (P.L.433, No.111), are
18 amended to read:

19 Section 7.1. Reinstatement of License, Certificate or
20 Registration.--Unless ordered to do so by Commonwealth Court or
21 an appeal therefrom, the board shall not reinstate the license,
22 certificate or registration of a person to practice [pharmacy]
23 pursuant to this act which has been revoked. Any person whose
24 license, certificate or registration has been revoked may apply
25 for reinstatement, after a period of at least five years, but
26 must meet all of the licensing qualifications of this act for
27 the license applied for, to include the examination requirement,
28 if he or she desires to practice at any time after such
29 revocation.

30 Section 8. Unlawful Acts.--It shall be unlawful for:

1 * * *

2 (2) Any person not duly licensed as a pharmacist, pursuant
3 to section 3 hereof, to engage in the practice of pharmacy,
4 including the preparing, compounding, dispensing, selling or
5 distributing at retail to any person any drug, except by a
6 pharmacy intern, pharmacy technician or such other authorized
7 personnel under the direct and [immediate] personal supervision
8 of a pharmacist: Provided, however, That nothing herein shall be
9 construed to prevent a duly licensed medical practitioner from
10 dispensing, compounding or otherwise giving any drug to his own
11 patients after diagnosis or treatment of said patient, if such
12 compounding, preparing and dispensing is done by said licensee
13 himself, nor shall anything herein prevent any person from
14 selling or distributing at retail household remedies or
15 proprietary medicines when the same are offered for sale or sold
16 in the original packages which have been put up ready for sale
17 to consumers, provided household remedies or proprietary
18 medicines shall not include any controlled substances or non-
19 proprietary drug under the act of April 14, 1972 (P.L.233,
20 No.64), known as "The Controlled Substance, Drug, Device and
21 Cosmetic Act."

22 * * *

23 (8) Any person, firm or corporation to use the title
24 "pharmacist", "assistant pharmacist", "pharmacy technician,"
25 "pharmacy technician trainee," "druggist"[,] or "apothecary",
26 except a person duly licensed as a pharmacist or registered as a
27 pharmacy technician in Pennsylvania, or any person to conduct or
28 transact business under a name which contains as part thereof
29 the words "drug store", "pharmacy", "drugs", "medicine store",
30 "medicines", "drug shop," "apothecary," "pharmaceutical,"

1 "homeopathic," "homeopathy" or any term having a similar
2 meaning, or in any manner by advertisement, display of show
3 globes or otherwise describe or refer to the place of the
4 conducted business or person, unless the place is a pharmacy
5 duly issued a permit by the State Board of Pharmacy.

6 * * *

7 Section 8.1. Injunction.--It shall be unlawful for any
8 person to practice or attempt to offer to practice pharmacy or
9 as a pharmacy technician, as defined in this act, without having
10 at the time of so doing a valid, unexpired, unrevoked and
11 unsuspended license or registration issued under this act. The
12 unlawful practice of pharmacy as defined in this act may be
13 enjoined by the courts on petition of the board or the
14 Commissioner of Professional and Occupational Affairs. In any
15 such proceeding it shall not be necessary to show that any
16 person is individually injured by the actions complained of. If
17 it is found that the respondent has engaged in the unlawful
18 practice of pharmacy, the court shall enjoin him or her from so
19 practicing unless and until he or she has been duly licensed.
20 Procedure in such cases shall be the same as in any other
21 injunction suit. The remedy by injunction hereby given is in
22 addition to any other civil or criminal prosecution and
23 punishment.

24 ~~Section 8. Section 9.1(a) and (c) introductory paragraph,~~ <—
25 ~~added June 29, 2002 (P.L.673, No.102), are amended and~~
26 ~~subsection (c) is amended by adding a paragraph to read:~~

27 ~~Section 9.1. Drug Therapy Protocols. (a) A [pharmacist]~~
28 ~~licensed pharmacist, individually, or in an institutional or~~
29 ~~non institutional setting shall be permitted to enter into a~~
30 ~~written agreement or protocol with a licensed physician~~

1 ~~authorizing the management of drug therapy in an institutional~~
2 ~~setting.~~

3 * * *

4 SECTION 8. SECTION 9.1(E) INTRODUCTORY PARAGRAPH, ADDED JUNE <—
5 29, 2002 (P.L.673, NO.102), IS AMENDED AND THE SUBSECTION IS
6 AMENDED BY ADDING A PARAGRAPH TO READ:

7 SECTION 9.1. DRUG THERAPY PROTOCOLS.--* * *

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

13 * * *

14 (13) Require a licensed pharmacist to provide to the board
15 satisfactory evidence of completion of all necessary training
16 required in the management of drug therapy for a disease ~~or~~, OR <—
17 FOR a condition or symptom of a disease, which is the subject of <—
18 the written agreement or protocol. A licensed pharmacist
19 practicing the management of drug therapy in an institutional
20 setting on the effective date of this paragraph shall not be
21 required to comply with the training requirement specified in
22 this paragraph.

23 * * *

24 Section 9. The act is amended by adding a section to read:

25 Section 9.3. Collaborative Drug Therapy Management.--(a) A
26 licensed pharmacist shall be permitted to enter into a
27 collaborative agreement with a licensed physician authorizing
28 the management of drug therapy for a disease ~~or~~, OR FOR a <—
29 condition or symptom of a disease, in a setting other than an <—
30 institutional setting.

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

4 (1) Be able to provide to the board satisfactory evidence of
5 training in the management of drug therapy for the disease or A <—
6 DISEASE, OR FOR A condition or symptom of a disease, which is <—
7 the subject of the collaborative agreement. <—

8 ~~(2) A licensed pharmacist practicing the management of drug~~
9 COLLABORATIVE AGREEMENT. A LICENSED PHARMACIST PRACTICING THE <—
10 MANAGEMENT OF DRUG therapy in an institutional setting on the
11 enactment EFFECTIVE DATE of this section shall not be required <—
12 to comply with this subsection PARAGRAPH. <—

13 ~~(3) (2) Complies with registration by the board. A list of~~ <—
14 registrants shall be accessible by the public.

15 ~~(4) (3) Of the continuing education credits completed as a~~ <—
16 condition of biennial renewal, has two continuing education
17 credits that focus on the management of drug therapy or focus on
18 a disease or, OR ON A condition or symptom of a disease, being <—
19 treated through drug therapy.

20 ~~(5) (4) Must utilize an area for consultation relating to~~ <—
21 the management of drug therapy that ensures the confidentiality
22 of the patient information being discussed.

23 (c) (1) (i) A pharmacist who is a party to a collaborative
24 agreement authorizing the management of drug therapy shall
25 obtain and maintain, to the satisfaction of the board,
26 professional liability insurance coverage in the minimum amount
27 of one million dollars (\$1,000,000) per occurrence or claims
28 made. The professional liability insurance coverage shall remain
29 in effect as long as that pharmacist is a party to a written
30 agreement or protocol authorizing the management of drug

1 therapy.

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

4 (2) The board shall accept from a pharmacist 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 (d) A licensed pharmacist may not provide economic
17 incentives to a licensed physician for the purpose of entering
18 into a collaborative agreement for the management of drug
19 therapy.

20 (e) The management of drug therapy pursuant to a
21 collaborative agreement shall be initiated by a written referral
22 from the physician to the pharmacist. The written referral shall
23 include the frequency in which the pharmacist must conduct the
24 management of drug therapy in person.

25 (f) The licensed physician who is a party to the
26 collaborative agreement authorizing the management of drug
27 therapy shall be in active practice and in good standing and the
28 collaborative agreement shall be within the scope of the
29 licensed physician's current practice.

30 (g) Participation in a collaborative agreement authorizing

1 the management of drug therapy shall be voluntary and no
2 licensed physician or pharmacist shall be required to
3 participate.

4 (h) A patient's records related to the management of drug
5 therapy may be maintained in an automated system.

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

10 (j) All patient records in the possession of a licensed
11 pharmacist providing the management of drug therapy must comply
12 with the Health Insurance Portability and Accountability Act of
13 1996 (Public Law 104-191, 110 Stat. 1936).

14 (k) The collaborative agreement must:

15 (1) Be between a licensed physician and a licensed
16 pharmacist.

17 (2) Comply with the requirements specified in section
18 9.1(e).

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

24 Section 10. No individual is required to be registered as a
25 pharmacy technician under section 2.1 of the act until two years
26 after the State Board of Pharmacy has promulgated regulations
27 under section 6 of this act.

28 Section 11. Nothing in this act shall be construed to
29 provide prescriptive authority to a licensed pharmacist.

30 Section 12. The State Board of Pharmacy shall promulgate

1 regulations to implement the ~~amendment of section 2.1 and 9.1(a)~~ <—
2 ADDITION OF SECTIONS 2.1 AND 9.3 of the act within 18 months of <—
3 the effective date of this section. The ~~amendment or~~ addition of <—
4 ~~section 2.1, 9.1(a)~~ SECTIONS 2.1 and 9.3 of the act, ~~except~~ <—
5 ~~9.3(b)(2) of the act,~~ shall not be enforceable by the State
6 Board of Pharmacy until the publication of final regulations.
7 Section 13. This act shall take effect in 60 days.