

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1250 Session of 2007

INTRODUCED BY KULA, EACHUS, KORTZ, SOLOBAY, MAHONEY, JOSEPHS, TANGRETTI, WALKO, FREEMAN, PRESTON, MOUL, SAYLOR, EVERETT, WATSON, GIBBONS, DALEY, SIPTROTH, HORNAMAN, FABRIZIO, JAMES AND PASHINSKI, MAY 8, 2007

AS REPORTED FROM COMMITTEE ON PROFESSIONAL LICENSURE, HOUSE OF REPRESENTATIVES, AS AMENDED, OCTOBER 31, 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; and further providing <—
8 for 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, ~~immediate~~ and personal supervision of a ←
7 pharmacist" 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 ~~immediate~~ availability on the ←
13 premises to direct the work of the supervised individual and to
14 respond to 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 ←
26 TO SECTION 9.3 OR, IF in an institutional setting, consistent ←
27 with the institution's assignment of clinical duties † pursuant ←
28 to a written agreement of 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~~ THERAPY[, CONSISTENT <—
14 with the testing standards of the institution. Managing drug
15 therapy shall be performed pursuant to a written agreement or
16 protocol as set forth in section 9.1 of this act.] therapy. <—
17 ~~Managing drug therapy in an institutional setting;~~ MONITORING <—
18 THE PATIENT'S VITAL SIGNS; AND PROVIDING EDUCATION AND TRAINING
19 TO THE PATIENT WHICH IS RELATED TO THE MANAGEMENT OF DRUG
20 THERAPY. MANAGING DRUG THERAPY UNDER SECTION 9.1 shall be
21 performed consistent with the institution's assignment of
22 clinical duties and ordering of laboratory tests and ordering or
23 performing other diagnostic tests necessary in the management of
24 drug therapy shall be consistent with the testing standards of
25 the institution.

26 * * *

27 ~~(15.1) "Non institutional setting" means a licensed pharmacy <—~~
28 ~~other than one located in an institution that employs one or~~
29 ~~more licensed pharmacists that may contract through that~~
30 ~~pharmacy to manage drug therapy under a written agreement with a~~

1 ~~physician.~~

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

3 Section 2.1. Registration and Permits for Pharmacy

4 Technicians.--(a) The board may register as a pharmacy

5 technician any individual who does the following:

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

7 (2) Files an application for licensure REGISTRATION, <—

8 subscribed by the individual under oath or affirmation,

9 containing information the board requires.

10 (3) Except as set forth in subsection (b), complies with all

11 of the following:

12 (i) Is not less than eighteen years of age and is a citizen <—

13 LEGAL RESIDENT of the United States. <—

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

15 (iii) Has satisfied the board that the applicant is of good

16 moral character and is not unfit or unable to practice as a

17 pharmacy technician by reason of the extent or manner of his use

18 of alcoholic beverages or controlled substances or by reason of

19 a physical or mental disability.

20 (iv) Has completed a pharmacy technician training program

21 approved by the board.

22 ~~(v) Has received certification from a certifying agency~~ <—

23 ~~approved by a nationally recognized accrediting agency approved~~

24 ~~by the board; or has successfully completed an examination~~

25 (V) HAS RECEIVED CERTIFICATION FROM A NATIONALLY RECOGNIZED <—

26 CERTIFYING AGENCY APPROVED BY THE BOARD.

27 (VI) HAS SUCCESSFULLY COMPLETED AN EXAMINATION approved by

28 the board.

29 ~~(vi) (VII) Examinations shall be administered in accordance~~ <—

30 with the requirements set forth in section 812.1(a) of the act

1 of April 9, 1929 (P.L.177, No.175), known as "The Administrative
2 Code of 1929."

3 (vii) (VIII) Has not been convicted of a felonious act ←
4 prohibited by the act of April 14, 1972 (P.L.233, No.64), known
5 as "The Controlled Substance, Drug, Device and Cosmetic Act," or
6 convicted of a felony relating to a controlled substance in a
7 court of law of the United States or any other state, territory
8 or country unless:

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

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

23 (b) The following apply:

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

26 (i) An individual who, at the time of filing an application,
27 has proof or registration, certification or licensure or its
28 equivalent as a pharmacy technician in another state, territory
29 or possession of the United States which has registration,
30 certification, licensure or equivalent requirements comparable

1 to those set forth in this section and regulations of the board.

2 (ii) An individual who:

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

5 (B) on the effective date of this section maintains a
6 current certification by a nationally recognized pharmacy
7 technician association.

8 (2) Notwithstanding subsection (a)(3)(ii), (iv) and (v), the
9 board shall issue a license REGISTRATION to an individual who: ←

10 (i) Has been employed as a pharmacy technician for a minimum
11 of 2,000 hours during the three years immediately preceding the
12 enactment of this act.

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

16 (c) A registration shall authorize the registrant to assist
17 in the practice of pharmacy under the direct, ~~immediate~~ and ←
18 personal supervision of a pharmacist.

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

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

22 (1) The board shall issue a temporary permit to practice as
23 a pharmacy technician trainee to an applicant who is seventeen
24 years of age or older and meets the requirements of subsection
25 (a)(3)(ii) and ~~(vi)~~ (III) and complies with the following: ←

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

29 (ii) The individual is employed by a pharmacy and
30 participates in a board-approved pharmacy technician training

1 program which may include an externship or internship program.

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

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

7 (4) A temporary permit shall authorize the permittee to
8 perform the duties of a pharmacy technician under the direct ←
9 immediate and personal supervision of a pharmacist.

10 (f) Identification requirements are as follows:

11 (1) A pharmacy technician shall wear a name tag that clearly
12 identifies the pharmacy technician with the title "licensed
13 pharmacy technician."

14 (2) A holder of a temporary permit shall wear a name tag
15 that clearly identifies the temporary permit holder with the
16 title "~~pharmacy~~ "REGISTERED PHARMACY technician trainee." ←

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

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

22 Section 3.2. Reporting of Multiple Licensure, REGISTRATION ←
23 OR ITS EQUIVALENT.--Any [licensed] pharmacist or pharmacy
24 technician of this Commonwealth who is also registered,
25 certified or licensed [to practice pharmacy] in any other state,
26 territory or country shall report this information to the board
27 on the biennial registration application. Any disciplinary
28 action taken in other states, territories and countries shall be
29 reported to the board on the biennial registration application
30 or within ninety days of final disposition, whichever is sooner.

1 Multiple [licensure] registration certification or licensure
2 shall be noted by the board on the [pharmacist's] LICENSEE'S OR ←
3 registrant's record, and such state, territory or country shall
4 be notified by the board of any disciplinary actions taken
5 against [said pharmacist] that licensee OR REGISTRANT in this ←
6 Commonwealth.

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

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

14 * * *

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

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

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

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

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

28 (v) Paying rebates to physicians or any other persons, or
29 the entering into any agreement with a medical practitioner or
30 any other person for the payment or acceptance of compensation

1 in any form for the recommending of the professional services of
2 either party;

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

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

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

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

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

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

28 [(xii) To accept employment as a pharmacist, or share or
29 receive compensation in any form arising out of, or incidental
30 to, his professional activities from any medical practitioner or

1 any other person or corporation in which one or more medical
2 practitioners have a proprietary or beneficial interest
3 sufficient to permit them to exercise supervision or control
4 over the pharmacist in his professional responsibilities and
5 duties;

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

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

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

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

26 (a.1) The board shall have the power to refuse, revoke or
27 suspend the registration of any pharmacy technician upon proof
28 satisfactory to it that the pharmacy technician has done any of
29 the following:

30 (1) Procured a person registration through fraud,

1 misrepresentation or deceit.

2 (2) Has been found guilty, pleaded guilty, entered a plea of
3 nolo contendere, or has received probation without verdict,
4 disposition in lieu of trial or an Accelerated Rehabilitative
5 Disposition in the disposition of felony charges, to any offense
6 in connection with the practice of pharmacy or any offense
7 involving moral turpitude before any court of record of any
8 jurisdiction.

9 (3) Is unfit to practice as a pharmacy technician because of
10 intemperance in the use of alcoholic beverages, controlled
11 substances or any other substance which impairs the intellect
12 and judgment to such an extent as to impair the performance of
13 professional duties.

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

30 (5) Has had a registration, certification or license to

1 practice as a pharmacy technician denied, revoked or suspended
2 by an appropriate pharmacy technician registration,
3 certification or licensing authority or has received
4 disciplinary action from an appropriate pharmacy technician
5 registration, certification or licensing authority.

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

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

12 * * *

13 (c) When the board finds that the registration,
14 certification or license [of any pharmacist] may be refused,
15 revoked or suspended under the terms of subsection (a) or (a.1),
16 the board may:

17 (1) Deny the application for a registration, certification
18 or license.

19 (2) Administer a public reprimand.

20 (3) Revoke, suspend, limit or otherwise restrict a
21 registration, certification or license as determined by the
22 board.

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

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

29 (6) Restore or reissue, in its discretion, a suspended
30 license [to practice pharmacy] or registration and impose any

1 disciplinary or corrective measure which it might originally
2 have imposed.

3 * * *

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

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

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

9 (1) To regulate the practice of pharmacy and of pharmacy
10 technicians;

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

13 (3) To examine, inspect and investigate all applications and
14 all applicants for licensure as pharmacists, pharmacies or
15 registration as pharmacy interns and pharmacy technicians, and
16 to grant certificates of licensure or registration to all
17 applicants whom it shall judge to be properly qualified;

18 (4) With the approval of the Commissioner of Professional
19 and Occupational Affairs, to prepare position descriptions,

20 employ inspectors who shall be licensed pharmacists OR ←
21 REGISTERED PHARMACY TECHNICIANS SUPERVISED BY LICENSED

22 PHARMACISTS and employ appropriate consultants to assist it for
23 any purposes which it may deem necessary, provided that the

24 board may not delegate any of its final decisionmaking
25 responsibilities to any consultant;

26 (4.1) TO REQUIRE THAT A PHARMACY TECHNICIAN HIRED FOR ←
27 PURPOSES OF INSPECTING LICENSED PHARMACIES IS HIRED WITH
28 CONSULTATION OF THE BOARD AND THAT THE PHARMACY TECHNICIAN:

29 (I) HAS BEEN EMPLOYED FULL TIME AS A PHARMACY TECHNICIAN IN
30 A LICENSED PHARMACY LOCATED IN THIS COMMONWEALTH FOR THE

1 IMMEDIATE PRIOR FIVE YEARS.

2 (II) HAS SUCCESSFULLY COMPLETED A BOARD OF PHARMACY
3 INSPECTOR TRAINING PROGRAM AND EXAMINATION DEMONSTRATING
4 REQUIRED KNOWLEDGE OF STATE PHARMACY LAW AND REGULATIONS.

5 (III) REPORTS DIRECTLY TO A SUPERVISOR WHO IS A PHARMACIST
6 LICENSED IN THIS STATE THAT ALSO SERVES AS AN INSPECTOR
7 PERFORMING TASKS AND DUTIES ASSOCIATED WITH THAT RESPONSIBILITY.

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

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

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

4 (8) To assist the regularly constituted enforcement agencies
5 of this Commonwealth in enforcing all laws pertaining to drugs,
6 controlled substances, and practice of pharmacy;

7 (8.1) To approve programs for the training of pharmacy
8 technicians.

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

13 * * *

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

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

17 (e) Notwithstanding any other provision, subsections (d.3),
18 (d.4), (d.5), (d.6), (d.7) and (d.8) shall not apply to pharmacy
19 technicians, EXCEPT AS THOSE SUBSECTIONS RELATE TO THE ←
20 PROFESSIONAL HEALTH MONITORING PROGRAM.

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

24 Section 7.1. Reinstatement of License, Certificate or
25 Registration.--Unless ordered to do so by Commonwealth Court or
26 an appeal therefrom, the board shall not reinstate the license,
27 certificate or registration of a person to practice [pharmacy]
28 pursuant to this act which has been revoked. Any person whose
29 license, certificate or registration has been revoked may apply
30 for reinstatement, after a period of at least five years, but

1 must meet all of the licensing qualifications of this act for
2 the license applied for, to include the examination requirement,
3 if he or she desires to practice at any time after such
4 revocation.

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

6 * * *

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

27 * * *

28 (8) Any person, firm or corporation to use the title
29 "pharmacist", "assistant pharmacist", "pharmacy technician,"
30 "pharmacy technician trainee," "druggist"[,] or "apothecary",

1 except a person duly licensed as a pharmacist or registered as a
2 pharmacy technician in Pennsylvania, or any person to conduct or
3 transact business under a name which contains as part thereof
4 the words "drug store", "pharmacy", "drugs", "medicine store",
5 "medicines", "drug shop," "apothecary," "pharmaceutical,"
6 "homeopathic," "homeopathy" or any term having a similar
7 meaning, or in any manner by advertisement, display of show
8 globes or otherwise describe or refer to the place of the
9 conducted business or person, unless the place is a pharmacy
10 duly issued a permit by the State Board of Pharmacy.

11 * * *

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

29 ~~Section 8. Section 9.1(a) of the act, added June 29, 2002~~ <—
30 ~~(P.L.673, No.102), is amended to read:~~

1 SECTION 8. SECTION 9.1(A) AND (E) INTRODUCTORY PARAGRAPH, <—
2 ADDED JUNE 29, 2002 (P.L.673, NO.102), ARE AMENDED AND
3 SUBSECTION (E) IS AMENDED BY ADDING A PARAGRAPH TO READ:

4 Section 9.1. Drug Therapy Protocols.--(a) A [pharmacist]
5 licensed pharmacist, individually, or in an institutional or
6 non-institutional setting shall be permitted to enter into a
7 written agreement or protocol with a licensed physician
8 authorizing the management of drug therapy in an institutional
9 setting.

10 * * *

11 (E) [WITHIN EIGHTEEN MONTHS OF THE EFFECTIVE DATE OF THIS <—
12 SECTION, THE] THE BOARD SHALL ADOPT REGULATIONS ESTABLISHING THE
13 PARAMETERS OF WRITTEN AGREEMENTS OR PROTOCOLS AUTHORIZED BY THIS
14 SECTION. SUCH PARAMETERS SHALL INCLUDE, BUT NOT BE LIMITED TO,
15 THE REQUIREMENT THAT WRITTEN AGREEMENTS OR PROTOCOLS:

16 * * *

17 (13) REQUIRE A LICENSED PHARMACIST TO PROVIDE TO THE BOARD
18 SATISFACTORY EVIDENCE OF COMPLETION OF ALL NECESSARY TRAINING
19 REQUIRED IN THE MANAGEMENT OF DRUG THERAPY FOR A DISEASE OR A
20 CONDITION OR SYMPTOM OF A DISEASE WHICH IS THE SUBJECT OF THE
21 WRITTEN AGREEMENT OR PROTOCOL. A LICENSED PHARMACIST PRACTICING
22 THE MANAGEMENT OF DRUG THERAPY IN AN INSTITUTIONAL SETTING ON
23 THE EFFECTIVE DATE OF THIS PARAGRAPH SHALL NOT BE REQUIRED TO
24 COMPLY WITH THE TRAINING REQUIREMENT SPECIFIED IN THIS
25 PARAGRAPH.

26 * * *

27 SECTION 9. THE ACT IS AMENDED BY ADDING A SECTION TO READ:

28 SECTION 9.3. COLLABORATIVE DRUG THERAPY MANAGEMENT.--(A) A
29 LICENSED PHARMACIST SHALL BE PERMITTED TO ENTER INTO A
30 COLLABORATIVE AGREEMENT WITH A LICENSED PHYSICIAN AUTHORIZING

1 THE MANAGEMENT OF DRUG THERAPY FOR A DISEASE OR A CONDITION OR
2 SYMPTOM OF A DISEASE IN A SETTING OTHER THAN AN INSTITUTIONAL
3 SETTING.

4 (B) A LICENSED PHARMACIST WHO IS A PARTY TO A COLLABORATIVE
5 AGREEMENT AUTHORIZING THE MANAGEMENT OF DRUG THERAPY MUST COMPLY
6 WITH THE FOLLOWING:

7 (1) BE ABLE TO PROVIDE TO THE BOARD SATISFACTORY EVIDENCE OF
8 TRAINING IN THE MANAGEMENT OF DRUG THERAPY FOR THE DISEASE OR
9 CONDITION OR SYMPTOM OF A DISEASE WHICH IS THE SUBJECT OF THE
10 COLLABORATIVE AGREEMENT.

11 (2) A LICENSED PHARMACIST PRACTICING THE MANAGEMENT OF DRUG
12 THERAPY IN AN INSTITUTIONAL SETTING ON THE ENACTMENT OF THIS
13 SECTION SHALL NOT BE REQUIRED TO COMPLY WITH THIS SUBSECTION.

14 (3) COMPLIES WITH REGISTRATION BY THE BOARD. A LIST OF
15 REGISTRANTS SHALL BE ACCESSIBLE BY THE PUBLIC.

16 (4) OF THE CONTINUING EDUCATION CREDITS COMPLETED AS A
17 CONDITION OF BIENNIAL RENEWAL, HAS TWO CONTINUING EDUCATION
18 CREDITS THAT FOCUS ON THE MANAGEMENT OF DRUG THERAPY OR FOCUS ON
19 A DISEASE OR CONDITION OR SYMPTOM OF A DISEASE BEING TREATED
20 THROUGH DRUG THERAPY.

21 (5) MUST UTILIZE AN AREA FOR CONSULTATION RELATING TO THE
22 MANAGEMENT OF DRUG THERAPY THAT ENSURES THE CONFIDENTIALITY OF
23 THE PATIENT INFORMATION BEING DISCUSSED.

24 (C) (1) (I) A PHARMACIST WHO IS A PARTY TO A COLLABORATIVE
25 AGREEMENT AUTHORIZING THE MANAGEMENT OF DRUG THERAPY SHALL
26 OBTAIN AND MAINTAIN, TO THE SATISFACTION OF THE BOARD,
27 PROFESSIONAL LIABILITY INSURANCE COVERAGE IN THE MINIMUM AMOUNT
28 OF ONE MILLION DOLLARS (\$1,000,000) PER OCCURRENCE OR CLAIMS
29 MADE. THE PROFESSIONAL LIABILITY INSURANCE COVERAGE SHALL REMAIN
30 IN EFFECT AS LONG AS THAT PHARMACIST IS A PARTY TO A WRITTEN

1 AGREEMENT OR PROTOCOL AUTHORIZING THE MANAGEMENT OF DRUG
2 THERAPY.

3 (II) FAILURE TO MAINTAIN INSURANCE COVERAGE AS REQUIRED
4 UNDER THIS SUBSECTION SHALL BE ACTIONABLE UNDER SECTION 5.

5 (2) THE BOARD SHALL ACCEPT FROM A PHARMACIST AS SATISFACTORY
6 EVIDENCE OF INSURANCE COVERAGE UNDER THIS SUBSECTION ANY AND ALL
7 OF THE FOLLOWING: SELF-INSURANCE, PERSONALLY PURCHASED
8 PROFESSIONAL LIABILITY INSURANCE, PROFESSIONAL LIABILITY
9 INSURANCE COVERAGE PROVIDED BY THE PHARMACIST'S EMPLOYER OR ANY
10 SIMILAR TYPE OF COVERAGE.

11 (3) THE BOARD SHALL ADOPT, BY REGULATION, STANDARDS AND
12 PROCEDURES ESTABLISHED BY THE INSURANCE COMMISSIONER FOR SELF-
13 INSURANCE. IN THE ABSENCE OF THESE STANDARDS AND PROCEDURES, THE
14 BOARD, AFTER CONSULTATION WITH THE INSURANCE COMMISSIONER, SHALL
15 ESTABLISH STANDARDS AND PROCEDURES BY REGULATION FOR SELF-
16 INSURANCE UNDER THIS SUBSECTION.

17 (D) A LICENSED PHARMACIST MAY NOT PROVIDE ECONOMIC
18 INCENTIVES TO A LICENSED PHYSICIAN FOR THE PURPOSE OF ENTERING
19 INTO A COLLABORATIVE AGREEMENT FOR THE MANAGEMENT OF DRUG
20 THERAPY.

21 (E) THE MANAGEMENT OF DRUG THERAPY PURSUANT TO A
22 COLLABORATIVE AGREEMENT SHALL BE INITIATED BY A WRITTEN REFERRAL
23 FROM THE PHYSICIAN TO THE PHARMACIST. THE WRITTEN REFERRAL SHALL
24 INCLUDE THE FREQUENCY IN WHICH THE PHARMACIST MUST CONDUCT THE
25 MANAGEMENT OF DRUG THERAPY IN PERSON.

26 (F) THE LICENSED PHYSICIAN WHO IS A PARTY TO THE
27 COLLABORATIVE AGREEMENT AUTHORIZING THE MANAGEMENT OF DRUG
28 THERAPY SHALL BE IN ACTIVE PRACTICE AND IN GOOD STANDING AND THE
29 COLLABORATIVE AGREEMENT SHALL BE WITHIN THE SCOPE OF THE
30 LICENSED PHYSICIAN'S CURRENT PRACTICE.

1 (G) PARTICIPATION IN A COLLABORATIVE AGREEMENT AUTHORIZING
2 THE MANAGEMENT OF DRUG THERAPY SHALL BE VOLUNTARY AND NO
3 LICENSED PHYSICIAN OR PHARMACIST SHALL BE REQUIRED TO
4 PARTICIPATE.

5 (H) A PATIENT'S RECORDS RELATED TO THE MANAGEMENT OF DRUG
6 THERAPY MAY BE MAINTAINED IN AN AUTOMATED SYSTEM.

7 (I) A LICENSED PHARMACIST WHO IS A PARTY TO THE
8 COLLABORATIVE AGREEMENT AUTHORIZING THE MANAGEMENT OF DRUG
9 THERAPY SHALL HAVE ACCESS TO THE RECORDS OF A PATIENT WHO IS THE
10 RECIPIENT OF THE MANAGEMENT OF DRUG THERAPY.

11 (J) ALL PATIENT RECORDS IN THE POSSESSION OF A LICENSED
12 PHARMACIST PROVIDING THE MANAGEMENT OF DRUG THERAPY MUST COMPLY
13 WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF
14 1996 (PUBLIC LAW 104-191, 110 STAT. 1936).

15 (K) THE COLLABORATIVE AGREEMENT MUST:

16 (1) BE BETWEEN A LICENSED PHYSICIAN AND A LICENSED
17 PHARMACIST.

18 (2) COMPLY WITH THE REQUIREMENTS SPECIFIED IN SECTION
19 9.1(E).

20 (3) SPECIFY THE TERMS UNDER WHICH A LICENSED PHARMACIST
21 PROVIDING DRUG THERAPY SERVICES IS PERMITTED TO ADJUST DRUG
22 REGIMEN OR TO ADJUST DRUG STRENGTH, FREQUENCY OF ADMINISTRATION
23 OR ROUTE WITHOUT PRIOR WRITTEN OR ORAL CONSENT BY THE
24 COLLABORATING PHYSICIAN.

25 Section 9 10. No individual is required to be registered as <—
26 a pharmacy technician under section 2.1 of the act until two
27 years after the State Board of Pharmacy has promulgated
28 regulations under section 6 of this act.

29 SECTION 11. NOTHING IN THIS ACT SHALL BE CONSTRUED TO <—
30 PROVIDE PRESCRIPTIVE AUTHORITY TO A LICENSED PHARMACIST.

1 Section ~~10~~ 12. The State Board of Pharmacy shall promulgate <—
2 regulations to implement the amendment of section 2.1 and 9.1(a)
3 of the act within 18 months of the effective date of this
4 section. THE AMENDMENT OR ADDITION OF SECTION 2.1, 9.1(A) AND <—
5 9.3 OF THE ACT, EXCEPT 9.3(B)(2) OF THE ACT, SHALL NOT BE
6 ENFORCEABLE BY THE STATE BOARD OF PHARMACY UNTIL THE PUBLICATION
7 OF FINAL REGULATIONS.

8 Section ~~11~~ 13. This act shall take effect in 60 days. <—