

45:14-40

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2003 **CHAPTER:** 280
NJSA: 45:14-40 (Regulation of pharmacists)
BILL NO: A570 (Substituted for S2598)

SPONSOR(S) Impreveduto and Quigley

DATE INTRODUCED: Pre-filed

COMMITTEE: **ASSEMBLY:** Independent Professions

SENATE: ----

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** June 30, 2003; Re-enacted 12-15-2003

SENATE: June 30, 2003; Re-enacted 1-8-2004

DATE OF APPROVAL: January, 14, 2004

FOLLOWING ARE ATTACHED IF AVAILABLE:

[FINAL TEXT OF BILL](#) (5th reprint enacted)
(Amendments during passage denoted by superscript numbers)

A570

[SPONSOR'S STATEMENT](#): (Begins on page 21 of original bill) [Yes](#)

COMMITTEE STATEMENT: [ASSEMBLY:](#) [Yes](#)

SENATE: No

FLOOR AMENDMENT STATEMENTS: Yes [3-13-2003](#)
[5-15-2003](#)
[5-22-2003](#)
[6-23-2003](#)

LEGISLATIVE FISCAL ESTIMATE: No

S2598

[SPONSOR'S STATEMENT](#): (Begins on page 25 of original bill) [Yes](#)

COMMITTEE STATEMENT: **ASSEMBLY:** No

[SENATE:](#) [Yes](#)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: No

FOLLOWING WERE PRINTED:

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REPORTS:

No

HEARINGS:

No

NEWSPAPER ARTICLES:

No

§§1-41 -
C.45:14-40
to 45:14-80
§42 - Repealer
§43 - Note to
all sections

P.L. 2003, CHAPTER 280, *approved January 14, 2004*
Assembly, No. 570 (*Fifth Reprint*)

1 AN ACT regulating and licensing pharmacists and repealing various
2 parts of the statutory law.

3

4 **BE IT ENACTED** by the Senate and General Assembly of the State
5 of New Jersey:

6

7 1. a. This act shall be known and may be cited as the "New Jersey
8 Pharmacy Practice Act."

9 b. The practice of pharmacy in this State is declared a health care
10 professional practice affecting the public health, safety and welfare and
11 is subject to regulation and control in the public interest. It is further
12 declared to be a matter of public interest and concern that the practice
13 of pharmacy merits and receives the confidence of the public and that
14 only qualified persons be permitted to engage in the practice of
15 pharmacy in this State. This act shall be liberally construed to carry
16 out these objectives and purposes.

17 c. It is the purpose of this act to promote, preserve and protect the
18 public health, safety and welfare by and through the effective control
19 and regulation of the practice of pharmacy, the licensure of
20 pharmacists and the permitting, control and regulation of all pharmacy
21 practice sites ⁴[,]⁴ in ⁴[or out of]⁴ this State ⁴[,]⁴ that engage in the
22 practice of pharmacy.

23

24 2. As used in this act:

25 "Administer" means the direct application of a drug to the body of
26 a patient or research subject by subcutaneous, intramuscular or
27 intradermal injection, inhalation ⁴[,] or⁴ ingestion ⁴[or any other
28 means]⁴ by a pharmacist engaged in collaborative practice or in
29 accordance with regulations ⁴[of] jointly promulgated by⁴ the board
30 and the State Board of Medical Examiners⁴.

31 "Automated medication device" means a discrete unit that performs
32 specific drug dispensing operations.

33 "Automated medication system" means any process that performs

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹ Assembly floor amendments adopted March 13, 2003.

² Assembly floor amendments adopted May 15, 2003.

³ Assembly floor amendments adopted May 22, 2003.

⁴ Senate floor amendments adopted June 23, 2003.

⁵ Assembly amendments adopted in accordance with Governor's recommendations December 11, 2003.

1 operations or activities, other than compounding or administration,
2 relative to the storage, packaging, dispensing and distribution of
3 medications and which collects, controls and maintains all transaction
4 information.

5 "Board of Pharmacy" or "board" means the New Jersey State Board
6 of Pharmacy.

7 "Certification" means a certification awarded by a recognized non-
8 government specialty organization to signify that a pharmacist has met
9 predetermined qualifications and to signify to the public that the
10 pharmacist is competent to practice in the designated specialty.

11 "Collaborative drug therapy management" means a written protocol
12 ¹directed on a voluntary basis by a patient's physician ⁴, with the
13 patient's consent,⁴ that is¹ between a patient's physician who is treating
14 the patient for a specific disease and a pharmacist for cooperative
15 management of a patient's drug, biological and device-related health
16 care needs, which ²[may include, but not be limited to] ⁴[includes²:]
17 shall be conducted in accordance with regulations jointly promulgated
18 by the board and the State Board of Medical Examiners and shall only
19 include the⁴ collecting, analyzing and monitoring of patient data;
20 ordering ⁴or performing⁴ of laboratory tests ²based on the standing
21 orders of a physician as set forth in the written protocol²; ordering
22 ⁴[or performing]⁴ of clinical tests ²based on the standing orders of a
23 physician as set forth in the written protocol, ⁴[which] provided those
24 laboratory⁴ tests are² ¹granted waived status in accordance with the
25 provisions of the "New Jersey Clinical Laboratory Improvement Act,"
26 P.L.1975, c.166 (C.45:9-42.26 et seq.)¹ ²and are for the treatment of
27 a disease state identified ⁴jointly⁴ by the board ⁴and the State Board
28 of Medical Examiners⁴ as subject to collaborative drug therapy
29 management²; ¹[prescribing,]¹ ²[initiating,]² modifying, continuing
30 or discontinuing drug or device therapy; and therapeutic drug
31 monitoring with appropriate modification to dose, dosage regimen,
32 dosage forms or route of administration. ¹The interpretation of
33 clinical or laboratory tests under a written protocol may ³only³ be
34 performed by a pharmacist ³[if so agreed to by the physician in the
35 protocol] in direct consultation with a physician³ .¹

36 "Compounding" means the preparation, mixing, assembling,
37 packaging or labeling of a drug or device as the result of a
38 practitioner's prescription or initiative based on the relationship of the
39 practitioner or patient with the pharmacist in the course of
40 professional practice or for the purpose of, or incident to, research,
41 teaching or chemical analysis and not for sale or dispensing.
42 Compounding also includes the preparation of drugs or devices in
43 anticipation of prescription drug orders based on routine, regularly
44 observed prescribing patterns. ⁵Nothing in this act is meant to limit a
45 prescriber's ability under pre-existing law to order a compounded
46 medication for use in the prescriber's practice, as permitted by State

1 and federal law.⁵

2 "Confidential information" means information that is identifiable as
3 to the patient involved that a pharmacist accesses, transmits or
4 maintains in a patient's record or which is communicated to or by the
5 patient as part of patient counseling.

6 "Credentialing" means the process by which an approved academic
7 institution awards a certificate to signify that the credentialed
8 pharmacist has completed the required courses, examinations or both,
9 that indicate advanced knowledge of a particular area of pharmacy.

10 "Deliver" or "delivery" means the actual ^{2, 2} constructive or
11 attempted transfer of a drug or device from one person to another,
12 whether or not for consideration.

13 "Device" means an instrument, apparatus, implement, machine,
14 contrivance, implant or other similar or related article, including any
15 component part or accessory, which is required under federal law to
16 bear the label "RX Only."

17 "Dispense" or "dispensing" means the procedure entailing the
18 interpretation of a practitioner's prescription order for a drug,
19 biological or device, and pursuant to that order the proper selection,
20 measuring, compounding, labeling and packaging in a proper container
21 for subsequent administration to, or use by, a patient.

22 ¹"Dosage form" means the physical formulation or medium in which
23 the product is intended, manufactured and made available for use,
24 including, but not limited to: tablets, capsules, oral solutions⁴[and
25 suspensions] , aerosols, inhalers, gels, lotions, creams, ointments,
26 transdermals and suppositories, and the particular form of the above
27 which utilizes a specific technology or mechanism to control, enhance
28 or direct the release, targeting, systemic absorption or other delivery
29 of a dosage regimen in the body^{4, 1}

30 "Drug or medication" means articles recognized as drugs in any
31 official compendium, or supplement thereto, designated from time to
32 time by the board for use in the diagnosis, cure, mitigation, treatment
33 or prevention of disease in humans or other animals; articles intended
34 for use in the diagnosis, cure, mitigation, treatment or prevention of
35 disease in humans or other animals; articles intended to affect the
36 structure or any function of the body of humans or other animals,
37 except that a food, dietary ingredient or dietary supplement, as those
38 terms are defined in 21 U.S.C.s.321, is not a drug solely because the
39 label or the labeling contains such a claim; and articles intended for use
40 as a component of and articles specified in this definition of "drug or
41 medication."

42 "Drug utilization review" includes, but is not limited to, the
43 following activities:

44 (1) Evaluation of prescription drug orders and patient records for
45 known allergies, rational therapy-contraindications, appropriate dose
46 and route of administration and appropriate directions for use;

1 (2) Evaluation of prescription drug orders and patient records for
2 duplication of therapy;

3 (3) Evaluation of prescription drug orders and patient records for
4 interactions between drug-drug, drug-food, drug-disease and adverse
5 drug reactions; and

6 (4) Evaluation of prescription drug orders and patient records for
7 proper utilization, including over- or under-utilization, and optimum
8 therapeutic outcomes.

9 "Extern" means any person who is in the fifth or sixth year of
10 college or the third or fourth professional year, at an accredited school
11 or college of pharmacy approved by the board, who is assigned to a
12 training site for the purpose of acquiring accredited practical
13 experience under the supervision of the school or college at which the
14 person is enrolled.

15 ⁴"Electronic means" means any electronic or digital transmission
16 format, including facsimile or computer generated messaging.⁴

17 "Immediate supervision" means a level of control which assures that
18 the pharmacist is physically present at the pharmacy practice site and
19 has the responsibility for ⁴[the]⁴ accuracy and safety with respect to
20 the actions of pharmacy technicians, interns and externs.

21 "Intern" means any person who has graduated from an accredited
22 school or college of pharmacy approved by the board, or if a foreign
23 pharmacy graduate, any person who has met all of the requirements of
24 the board, and who is being trained by an approved preceptor for the
25 purpose of acquiring accredited practical experience and who has first
26 registered for that purpose with the board.

27 "Labeling" means the process of preparing and affixing a label to
28 any drug container, exclusive however, of the labeling by a
29 manufacturer, packer or distributor of a non-prescription drug or
30 commercially packaged legend drug or device.

31 ¹["Licensed or permitted non-resident pharmacy" means a
32 pharmacy located outside this State that solicits, advertises, ships,
33 mails or delivers drugs pursuant to a valid prescription into this
34 State.]¹

35 "Licensure" means the process by which the board grants
36 permission to an individual to engage in the practice of pharmacy upon
37 finding that the applicant has attained the degree of competency
38 necessary to ensure that the public health, safety and welfare will be
39 protected.

40 "Medication error" means a preventable event that may cause or
41 lead to inappropriate use of a medication or patient harm while the
42 medication is in the control of the practitioner, patient or consumer.

43 "Medication order" means a prescription for a specific patient in an
44 institutional setting.

45 ²"Modifying" means to change a specific drug, the dosage, or route
46 of delivery of a drug currently being administered for an existing

1 diagnosis pursuant to a collaborative drug therapy management.²

2 "Non-prescription drug or device" means a drug or device which
3 may be obtained without a prescription and which is labeled for
4 consumer use in accordance with the requirements of the laws and
5 rules of this State and the federal government.

6 "Permit" means the authorization granted by the board to a site to
7 engage in the practice of pharmacy.

8 "Person" means an individual, corporation, partnership, association
9 or any other legal entity including government.

10 "Pharmaceutical care" means the provision by a pharmacist of drug
11 therapy review and other related patient care services intended to
12 achieve positive outcomes related to the treatment, cure or prevention
13 of a disease; control, elimination or reduction of a patient's symptoms;
14 or arresting or slowing of a disease process as defined by the rules and
15 regulations of the board.

16 "Pharmacist" means an individual currently licensed by this State to
17 engage in the practice of pharmacy.

18 "Pharmacist-in-charge" means a pharmacist who accepts
19 responsibility for the operation of a pharmacy practice site in
20 conformance with all laws and rules pertinent to the practice of
21 pharmacy and the distribution of drugs.

22 "Pharmacist in collaborative practice" means a pharmacist engaged
23 in the collaborative drug therapy management of a patient's drug,
24 biological and device-related health care needs pursuant to a written
25 protocol, in collaboration with a licensed physician and in accordance
26 with the ⁴[board's]⁴ regulations ⁴jointly promulgated by the board and
27 the State Board of Medical Examiners⁴.

28 "Pharmacy practice site" means any place in ²[or outside of]² this
29 State ⁴[²or another state²]⁴ where drugs are dispensed or
30 pharmaceutical care is provided by a licensed pharmacist ⁴, but shall
31 not include a medical office under the control of a licensed physician⁴.

32 "Pharmacy technician" means an individual working in a pharmacy
33 practice site who, under the immediate supervision of a pharmacist,
34 assists in pharmacy activities ¹as¹ permitted by ¹section 41 of this act
35 and¹ the rules and regulations of the board that do not require the
36 professional judgment of a pharmacist.

37 "Practice of pharmacy" means a health care service by a pharmacist
38 that includes ¹[, but is not limited to]¹: compounding, dispensing and
39 labeling of drugs, biologicals, radio pharmaceuticals or devices;
40 overseeing automated medication systems; interpreting and evaluating
41 prescriptions; administering and distributing drugs, biologicals and
42 devices; maintaining prescription drug records; advising and consulting
43 on the therapeutic values, content, hazards and uses of drugs,
44 biologicals and devices; managing and monitoring drug therapy;
45 collecting, analyzing and monitoring patient data; performing drug
46 utilization reviews; storing prescription drugs and devices; supervising

1 technicians, interns and externs; and such other acts, services,
2 operations or transactions necessary, or incidental to, providing
3 pharmaceutical care and education. In accordance with written
4 guidelines or protocols established with a licensed physician, the
5 "practice of pharmacy" also includes ¹[:] collaborative drug therapy
6 management including^{1 2}[initiating,]^{2 1}[prescribing,]¹ modifying,
7 continuing or discontinuing drug or device therapy; ¹[collaborative
8 drug therapy management;]¹ ordering ⁴or performing⁴ of laboratory
9 tests ⁴under collaborative drug therapy management⁴; and ordering
10 ⁴[and performance of]⁴ clinical tests ⁴excluding laboratory tests,
11 unless those tests are part of collaborative drug therapy management⁴.

12 "Practitioner" means an individual currently licensed, registered or
13 otherwise authorized by the jurisdiction in which the individual
14 practices to administer or prescribe drugs in the course of professional
15 practice.

16 "Preceptor" means an individual who is a pharmacist, meets the
17 qualifications under the rules and regulations of the board, and
18 participates in the instructional training of pharmacy interns and
19 externs.

20 "Prescription" means a lawful order of a practitioner for a drug, a
21 device or diagnostic agent for a specific patient.

22 "Prescription drug" or "legend drug" means a drug which, under
23 federal law, is required to be labeled prior to being delivered to the
24 pharmacist, with either of the following statements: "Rx Only" or
25 "Caution: Federal law restricts this drug to use by, or on the order of,
26 a licensed veterinarian" or is required by any applicable federal or state
27 law, rule or regulation to be dispensed pursuant to a prescription drug
28 order or is restricted to use by a practitioner only.

29 "Registration" means the process of making a list or being enrolled
30 in an existing list.

31 ¹"Therapeutic interchange" means the substitution and dispensing
32 of a ⁴drug⁴ chemically dissimilar ²[but clinically equivalent]^{2 4}[drug
33 than] ⁴from⁴ the prescription drug originally prescribed.¹

34

35 3. The board shall enforce the provisions of this act. The board
36 shall have all of the duties, powers and authority specifically granted
37 by or necessary for the enforcement of this act, as well as such other
38 duties, powers and authority as it may be granted from time to time by
39 applicable law.

40

41 4. a. The board shall consist of eleven members, two of whom
42 shall be public members and one of whom shall be a state executive
43 department member appointed pursuant to the provisions of P.L.1971,
44 c.60 (C.45:1-2.1 et seq.). Each of the remaining eight members shall
45 be pharmacists. Each pharmacist member shall have at least five years
46 of experience in the practice of pharmacy in this State after licensure,

1 and shall at the time of appointment and throughout their tenure: be
2 currently licensed and in good standing to engage in the practice of
3 pharmacy in this State, and be actively engaged in the practice of
4 pharmacy in this State.

5 b. The Governor shall appoint the members of the board. Every
6 state professional pharmacy association may send to the Governor the
7 names of pharmacists having the qualifications required by this section,
8 whom the Governor may appoint to fill any vacancy occurring in the
9 board. In appointing members to the board to fill vacancies of
10 members who engage in the practice of pharmacy, the Governor shall
11 appoint members so that the membership of the board includes, at all
12 times, at least one pharmacist employed by a chain drug retailer who
13 owns or operates seven or more pharmacy practice sites, one
14 pharmacist who is employed by a health care system and one
15 pharmacist who owns a pharmacy practice site in this State.

16 c. Except for the members first appointed, members of the board
17 shall be appointed for a term of five years, except that members of the
18 board who are appointed to fill vacancies which occur prior to the
19 expiration of a former member's full term shall serve the unexpired
20 portion of that term. The terms of the members of the board shall be
21 staggered, so that the terms of no more than three members shall
22 expire in any year. Each member shall serve until a successor is
23 appointed and qualified. The present members of the board appointed
24 pursuant to R.S.45:14-1 et seq. shall serve the balance of their terms.
25 Any present board member appointed initially for a term of less than
26 five years shall be eligible to serve for two additional full terms. No
27 member of the board shall serve more than two consecutive full terms.
28 The completion of the unexpired portion of a full term shall not
29 constitute a full term for purposes of this subsection.

30 d. The Governor may remove a member of the board after a
31 hearing for misconduct, incompetency, neglect of duty or for any other
32 sufficient cause.

33

34 5. a. The board shall annually¹ elect from among¹ its members
35 a president and ¹[other officers that it deems appropriate and
36 necessary to the conduct of its business. The president of the board
37 shall preside at all meetings of the board and shall be responsible for
38 the performance of all of the duties and functions of the board required
39 or permitted by this act. Each additional officer elected by the board
40 shall perform those duties normally associated with his position and
41 those other duties assigned from time to time by the board. Officers
42 elected by the board shall serve terms of one year commencing with
43 the day of their election and ending upon election of their successors
44 and shall serve no more than two consecutive full terms in each office
45 to which they are elected] vice-president¹.

46 b. The position of executive director shall be held by a pharmacist

1 licensed in the State of New Jersey. The executive director shall be
2 responsible for the performance of the administrative functions of the
3 board and those other duties that the board may direct.

4
5 6. Each member of the board shall receive compensation pursuant
6 to section 2 of P.L. 1977, c. 285 (C. 45:1-2.5) of \$150 per day for
7 each day on which the member is engaged in performance of the
8 official duties of the board, and shall be reimbursed for all reasonable
9 and necessary expenses incurred in connection with the discharge of
10 those official duties.

11
12 7. The board shall meet at least once every month to transact its
13 business. The board shall meet at those additional times that it may
14 determine. Additional meetings may be called by the president of the
15 board or by two-thirds of the members of the board.

16
17 8. The board shall make, adopt, amend and repeal those rules and
18 regulations necessary for the proper administration and enforcement
19 of this act. Those rules and regulations shall be promulgated in
20 accordance with the "Administrative Procedure Act," P.L.1968, c.410
21 (C.52:14B-1 et seq.). ⁴Rules pertaining to collaborative drug therapy
22 management and administration of drugs by pharmacists shall be
23 jointly promulgated by the board and the State Board of Medical
24 Examiners.⁴

25
26 9. a. The board shall be responsible for the control and regulation
27 of the practice of pharmacy in this State including, but not limited to,
28 the following:

29 (1) The licensing by examination or by license transfer of
30 applicants who are qualified to engage in the practice of pharmacy
31 under the provisions of this act;

32 (2) The renewal of licenses to engage in the practice of pharmacy;

33 (3) The establishment and enforcement of professional standards
34 and rules of conduct of pharmacists engaged in the practice of
35 pharmacy;

36 (4) The establishment of requirements for pharmacists to engage
37 in collaborative practice;

38 (5) The establishment of requirements ⁴jointly promulgated with
39 the State Board of Medial Examiners⁴ for pharmacists to administer
40 drugs directly to patients;

41 (6) The enforcement of those provisions of this act relating to the
42 conduct or competence of pharmacists practicing in this State, and the
43 suspension, revocation, failure to renew or restriction of licenses to
44 engage in the practice of pharmacy pursuant to the provisions of
45 P.L.1978, c.73 (C.45:1-14 et seq.);

46 (7) The regulation of pharmacy practiced through any

1 technological means;

2 (8) The regulation and control of automated medication systems
3 and automated medication devices within or outside of pharmacy
4 practice sites;

5 (9) The right to seize any drugs and devices found by the board to
6 constitute an imminent danger to the public health and welfare;

7 (10) The establishment of minimum specifications for record
8 keeping, prescription and ¹patient¹ profile record maintenance,
9 pharmacy practice sites including, but not limited to, the physical
10 premises, technical equipment, environment, supplies, personnel and
11 procedures for the storage, compounding and dispensing of drugs or
12 devices, and for the monitoring of drug therapy;

13 (11) The inspection of any pharmacy practice site at all reasonable
14 hours for the purpose of determining if any provisions of the laws
15 governing the legal distribution of drugs or devices or the practice of
16 pharmacy are being violated. The board, its officers, inspectors and
17 representatives shall cooperate with all agencies charged with the
18 enforcement of the laws of the United States, of this State, and of all
19 other states relating to drugs, devices and the practice of pharmacy;

20 (12) The inspection of prescription files and the prescription
21 records of a pharmacy and the removal from the files and taking
22 possession of any original prescription, ⁵[⁴with the consent of the
23 patient.⁴]⁵ providing that the authorized agent removing or taking
24 possession of an original prescription shall place in the file from which
25 it was removed a copy certified by that person to be a true copy of the
26 original prescription removed; provided further, that the original copy
27 shall be returned by the board to the file from which it was removed
28 after it has served the purpose for which it was removed;

29 (13) The establishment of requirements for patient counseling,
30 patient profiles and drug utilization reviews; ¹[and]¹

31 (14) The establishment of regulations to protect the health and
32 safety of pharmacy patients ¹; and

33 (15) The prescribing or changing of the ⁴[charges] ⁴fees ⁴for
34 examinations, certifications, licensures, renewals and other services
35 performed pursuant to P.L.1974, c.46 (C.45:1-3.1et seq.) ⁴and this
36 act⁴ ¹.

37 b. The board shall have those other duties, powers and authority
38 as may be necessary to the enforcement of this act and to the
39 enforcement of rules and regulations of the board, which may include,
40 but not be limited to, the following:

41 (1) The determination and issuance of standards, recognition and
42 approval of degree programs of schools and colleges of pharmacy
43 whose graduates shall be eligible for licensure in this State, and the
44 specifications and enforcement of requirements for practical training,
45 including internships;

46 (2) The registration of externs, interns, pharmacy preceptors and

1 pharmacy technicians;

2 (3) The regulation of the training, qualifications and conduct of
3 applicants, externs, interns, pharmacy preceptors and pharmacy
4 technicians;

5 (4) The collection of professional demographic data;

6 (5) The joining with those professional organizations and
7 associations organized to promote the improvement of the standards
8 of the practice of pharmacy for the protection of the health and
9 welfare of the public or whose activities assist and facilitate the work
10 of the board;

11 (6) The establishment of a bill of rights for patients concerning the
12 health care services a patient may expect in regard to pharmaceutical
13 care;

14 (7) The engagement in activities to educate consumers, to assist
15 them in obtaining information necessary to make decisions about
16 medication issues;

17 (8) The ¹[assurance of the ongoing professional competency of
18 licensees or registrants] establishment of standards for the continuing
19 education of registered pharmacists¹;

20 (9) The establishment of rules and regulations for extraordinary
21 emergency situations that interfere with the ability to practice under
22 the current rules and regulations;

23 (10) The establishment of guidelines for board approved pilot
24 programs. The guidelines shall be complied with to implement a
25 program that may not be presently acknowledged in this act or its rules
26 or regulations; and

27 (11) The assurance that any credentialing or certification of a
28 pharmacist is not misleading to the public.

29 c. (1) The board may place under seal all drugs, biologicals, radio
30 pharmaceuticals or devices that are owned by or in the possession,
31 custody or control of a licensee or permit holder at the time his license
32 or permit is suspended or revoked or at the time the board refused to
33 renew his license. Except as otherwise provided in this section, drugs,
34 biologicals, radio pharmaceuticals or devices that are sealed pursuant
35 to this paragraph shall not be disposed of until appeal rights under the
36 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.)
37 have expired, or an appeal filed pursuant to that act has been
38 determined. The court, involved in an appeal filed pursuant to the
39 "Administrative Procedure Act," may order the board, during the
40 pendency of the appeal, to sell sealed drugs, biologicals and radio
41 pharmaceuticals that are perishable. The proceeds of a sale shall be
42 deposited with the court.

43 (2) Notwithstanding any provisions of this act to the contrary,
44 whenever a duly authorized representative of the board finds, or has
45 probable cause to believe, that any drug or device is outdated,
46 adulterated or misbranded within the meaning of the "Federal Food,

1 Drug, and Cosmetic Act," 21 U.S.C.s.301 et seq., the representative
2 shall affix to that drug or device a tag or other appropriate marking
3 giving notice that the article is or is suspected of being outdated,
4 adulterated or misbranded, had been detained or embargoed, and
5 warning all persons not to remove or dispose of the article by sale or
6 otherwise until provision for removing or disposal is given by the
7 board, its agent or the court. No person shall remove or dispose of an
8 embargoed drug or device by sale or otherwise without the permission
9 of the board or its agent or, after summary proceedings have been
10 instituted, without permission of the court.

11 (3) When a drug or device detained or embargoed under paragraph
12 (2) of this subsection c. has been declared by the representative to be
13 outdated, adulterated or misbranded, the board shall, as soon as
14 practical thereafter, petition the judge of the court in which
15 jurisdiction the article is detained or embargoed for an order for
16 condemnation of that article. If the judge determines that this drug or
17 device so detained or embargoed is not adulterated, outdated or
18 misbranded, the board shall direct the immediate removal of the tag or
19 other marking.

20 (4) If the court finds that a detained or embargoed drug or device
21 is adulterated, outdated or misbranded, that drug or device, after entry
22 of the decree, shall be destroyed at the expense of the owner under the
23 supervision of a board representative and all court costs and fees,
24 storage and other proper expenses shall be borne by the owner of that
25 drug or device. When the ⁴[outdated] outdating⁴, adulteration or
26 misbranding can be corrected by proper labeling or processing of the
27 drug or device, the court, after entry of the decree and after the costs,
28 fees and expenses have been paid and a good and sufficient bond has
29 been posted, may direct that the drug or device be delivered to the
30 owner thereof for labeling or processing under the supervision of a
31 board representative. Expense of that supervision shall be paid by the
32 owner. The bond shall be returned to the owner of the drug or device
33 on representation to the court by the board that the drug or device is
34 no longer in violation of the embargo and the expense of supervision
35 has been paid.

36 d. Except as otherwise provided to the contrary, the board shall
37 exercise all of its duties, powers and authority in accordance with the
38 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
39 seq.).

40 ¹[e. The board shall annually report to the Governor and to all
41 interested parties upon the condition of pharmacy practice in the State,
42 which report shall embrace a detailed statement of the receipts and
43 expenditures of the board.]¹

44

45 10. a. Except as otherwise provided in this act, it shall be unlawful
46 for any individual to engage in the practice of pharmacy unless

1 currently licensed to practice under the provisions of this act.

2 b. ¹The provisions of this act shall not apply to the sale of any drug
3 by a manufacturer or wholesaler or pharmacy to each other or to a
4 physician, dentist, veterinarian or other person licensed to prescribe
5 such drugs in their ²[pharmaceutical] professional² practice.

6 c.¹ Practitioners authorized under the laws of this State to
7 compound drugs and to dispense drugs directly to their patients in the
8 practice of their respective professions shall meet the ⁴standards
9 established by their respective licensing boards with respect to storage,
10 handling, security, counseling, labeling, packing and record keeping
11 requirements for the dispensing of drugs, or if no such standards exist,
12 the⁴ same storage, handling, security, counseling, labeling,
13 packaging¹ and record keeping requirements for the dispensing of
14 drugs applicable to pharmacists.

15

16 11. To obtain a license to engage in the practice of pharmacy, the
17 applicant shall:

18 a. Have submitted a written application in the form prescribed by
19 the board;

20 b. Have attained the age of 18 years;

21 c. Be of good moral character;

22 d. Have graduated and received a professional degree from a
23 college or school of pharmacy that has been approved by the board;

24 e. Have completed an internship or other program that has been
25 approved by the board, or demonstrated to the board's satisfaction
26 experience in the practice of pharmacy which meets or exceeds the
27 minimum internship requirements of the board;

28 f. Have successfully passed an examination or examinations
29 ¹[given] as determined¹ by the board; and

30 g. Have paid the fees specified by the board for the examination
31 and any related materials, and have paid for the issuance of the license.

32

33 12. ¹[a. The examination for licensure shall be given by the board
34 at least two times during each year. The board shall determine the
35 content and subject matter of each examination, and the place, time
36 and date of administration of the examination as defined by
37 regulations.

38 b.]¹ The examination ¹for licensure¹ shall ¹[be prepared to]¹
39 measure the competence of the applicant to engage in the practice of
40 pharmacy. The board may employ, cooperate and contract with any
41 organization or consultant in the preparation and grading of an
42 examination, but shall retain the sole discretion and responsibility for
43 determining which applicants have successfully passed the
44 examination.

45

46 13. a. All applicants for licensure by examination shall obtain

1 practical experience in the practice of pharmacy under terms and
2 conditions determined by the board.

3 b. The board may establish licensure requirements for interns and
4 standards for internship, or any other experiential program necessary
5 to qualify an applicant for the licensure examination, and shall also
6 determine the qualifications of preceptors used in practical experience
7 programs.

8

9 14. a. In order for a pharmacist currently licensed in another
10 jurisdiction to obtain a license as a pharmacist by license transfer in
11 this State, an applicant shall:

12 (1) Have submitted a written application in the form prescribed by
13 the board;

14 (2) Have attained the age of 18 years;

15 (3) Have good moral character;

16 (4) ¹[Have possessed at the time of initial licensure as a pharmacist
17 all the qualifications necessary to have been eligible for licensure at
18 that time in this State;

19 (5)]¹ Have engaged in the practice of pharmacy for a period of at
20 least 1,000 hours within the last two years or have met, immediately
21 prior to application, the internship requirements of this State within
22 the one-year period immediately preceding the date of application;

23 ¹[(6)] (5)¹ Have presented to the board proof of initial licensure
24 by examination and proof that the license is in good standing;

25 ¹[(7)] (6)¹ Have presented to the board proof that any other
26 license granted to the applicant by any other state has not been
27 suspended, revoked or otherwise restricted for any reason except
28 nonrenewal or for the failure to obtain the required continuing
29 education credits in any state where the applicant is currently licensed
30 but not engaged in the practice of pharmacy;

31 ¹[(8)] (7)¹ Have paid the fees specified by the board;¹[and

32 (9)] (8)¹ Have graduated and received a professional degree from
33 a college or school of pharmacy approved by the board ¹; and

34 (9) Have met any other requirements as established by the board
35 by regulation¹.

36 b. No applicant shall be eligible for license transfer unless the
37 ¹[state in which the applicant is originally licensed as a pharmacist
38 granted licensure according to substantially equivalent requirements as
39 this State at that time. The]¹ applicant ¹[shall also hold] holds ¹a
40 current valid license in a state that grants licensure transfer to
41 pharmacists duly licensed by examination in this State.

42 ¹c. In order for a pharmacist applicant with a pharmacy degree
43 from a foreign country or a college of pharmacy not approved by the
44 board to obtain a license as a pharmacist, that applicant shall meet
45 those requirements as established by the board by regulation.¹

46

1 15. a. The board shall require each person registered as a
2 pharmacist, as a condition for biennial renewal certification, to
3 complete ¹[30 credits of]¹ continuing pharmacy education during each
4 biennial period immediately preceding the date of renewal and submit
5 proof thereof to the board.

6 b. The board shall:

7 (1) Establish standards for continuing pharmacy education,
8 including the ¹number of credits, the¹ subject matter and content of
9 courses of study, the selection of instructors and the type of
10 continuing education credits required of a registered pharmacist as a
11 condition of biennial registration;

12 (2) Approve educational programs offering credit towards
13 continuing pharmacy education requirements; and

14 (3) Approve other equivalent educational programs, including, but
15 not limited to, home study courses, and establish procedures for the
16 issuance of credit upon satisfactory proof of the completion of these
17 programs. In the case of ¹continuing¹ education courses and
18 programs, each hour of instruction shall be equivalent to one credit.

19 c. (1) The board shall only approve programs that are provided on
20 a nondiscriminatory basis. The board shall permit any pharmacy
21 association or organization offering a continuing pharmacy education
22 program approved by the board pursuant to subsection b. of this
23 section to impose a reasonable differential in registration fees for
24 courses upon registered pharmacists who are not members of that
25 pharmacy association or organization. The board may approve
26 programs held within or outside the State.

27 (2) In no event shall the board grant credits for, or approve as, a
28 component of a continuing education program:

29 (a) participation in a routine business portion of a meeting of a
30 pharmacy association or organization; or

31 (b) any presentation that is offered to sell a product or promote a
32 business enterprise.

33 d. (1) The board may, in its discretion, waive requirements for
34 continuing education on an individual basis for reasons of hardship,
35 such as illness or disability, retirement of the registration certificate,
36 or any other good cause.

37 (2) The board shall not require completion of continuing education
38 credits for an initial renewal of registration.

39 (3) If a pharmacist completes a number of continuing education
40 credit hours in excess of the number required ¹[by subsection a. of this
41 section] for a biennial period¹, the board may allow, by rule or
42 regulation, credits to be carried over to satisfy the pharmacist's
43 continuing education requirement for the next biennial renewal period,
44 but shall not be applicable thereafter.

45
46 16. a. A practitioner practicing in this State shall use non-

1 reproducible, non-erasable safety paper New Jersey Prescription
2 Blanks bearing that practitioner's license number whenever the
3 practitioner issues prescriptions for controlled dangerous substances,
4 prescription legend drugs or other prescription items. The prescription
5 blanks shall be secured from a vendor approved by the Division of
6 Consumer Affairs in the Department of Law and Public Safety.

7 b. A licensed practitioner practicing in this State shall maintain a
8 record of the receipt of New Jersey Prescription Blanks. The
9 practitioner shall notify the Office of Drug Control in the Division of
10 Consumer Affairs as soon as possible but no later than 72 hours of
11 being made aware that any New Jersey Prescription Blank in the
12 practitioner's possession has been stolen. Upon receipt of notification,
13 the Office of Drug Control shall take appropriate action, including
14 notification to the Department of Human Services and the Attorney
15 General.

16

17 17. a. Prescriptions issued by a health care facility licensed
18 pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) shall be written on
19 non-reproducible, non-erasable safety paper New Jersey Prescription
20 Blanks. The prescription blanks shall be secured from a vendor
21 approved by the Division of Consumer Affairs in the Department of
22 Law and Public Safety. The New Jersey Prescription Blanks shall bear
23 the unique provider number assigned to that health care facility for the
24 issuing of prescriptions for controlled dangerous substances,
25 prescription legend drugs or other prescription items.

26 b. A health care facility shall maintain a record of the receipt of
27 New Jersey Prescription Blanks. The health care facility shall notify
28 the Office of Drug Control in the Division of Consumer Affairs as
29 soon as possible but no later than 72 hours of being made aware that
30 any New Jersey Prescription Blank in the facility's possession has been
31 stolen. Upon receipt of notification, the Office of Drug Control shall
32 take appropriate action including notification to the Department of
33 Human Services and the Attorney General.

34

35 18. A prescription issued by a practitioner or health care facility
36 ⁴licensed in New Jersey⁴ shall not be filled by a pharmacist unless the
37 prescription is issued on a New Jersey Prescription Blank bearing the
38 practitioner's license number or the unique provider number assigned
39 to a health care facility.

40 19. a. Nothing contained in this act shall preclude a practitioner
41 from transmitting to a pharmacist by telephone or electronic means a
42 prescription, as otherwise authorized by law, if that practitioner
43 provides the practitioner's Drug Enforcement Administration
44 registration number ⁴[or] and the⁴ practitioner's license number, ¹or
45 any other federally identified number,¹ as appropriate, to the
46 pharmacist at the time the practitioner transmits the prescription.

1 b. ¹[No] Except as may be otherwise permitted by law, no ¹
2 prescription for any ¹[narcotic drug, except as provided in section 15
3 of P.L.1970, c.226 (C.24:21-15),] Schedule II controlled dangerous
4 substance¹ shall be given or transmitted to pharmacists, in any other
5 manner, than in writing signed by the practitioner giving or
6 transmitting the same, nor shall such prescription be renewed or
7 refilled. The requirement in this subsection that a prescription for any
8 ¹[narcotic drug] controlled dangerous substance¹ be given or
9 transmitted to pharmacists in writing signed by the practitioner ⁴[,]⁴
10 shall not apply to a prescription for a Schedule II drug ¹[written for
11 a long-term care facility resident or hospital patient]¹ if that
12 prescription is transmitted or prepared in compliance with federal
13 ¹[Drug Enforcement Administration regulations 21 C.F.R. 1306.11(d),
14 (e), (f) and (g)] and State regulations¹.

15

16 20. The Division of Consumer Affairs in the Department of Law
17 and Public Safety shall establish the format for uniform, non-
18 reproducible, non-erasable safety paper prescription blanks, to be
19 known as New Jersey Prescription Blanks, which format shall include
20 an identifiable logo or symbol that will appear on all prescription
21 blanks. The division shall approve a sufficient number of vendors to
22 ensure production of an adequate supply of New Jersey Prescription
23 Blanks for practitioners and health care facilities statewide.

24

25 ¹21. A pharmacist may dispense a prescription in a different dosage
26 form than originally prescribed if the pharmacist notifies the prescriber
27 no later than 48 hours following the dispensing of the prescription ²,
28 provided the dosage form dispensed has the ⁴[same approximate]
29 appropriate⁴ drug release rate². ¹

30

31 ¹22. In establishing requirements for pharmacists to engage in
32 collaborative practice as provided in paragraph (4) of subsection a. of
33 section 9 of this act, the board shall include in these requirements, but
34 not be limited to, provisions that any written protocol between a
35 physician and pharmacist:

36 a. is agreed to by both the physician and the pharmacist ⁴with the
37 consent of the patient⁴;

38 b. identifies, by name and title, each physician and each pharmacist
39 who is permitted to participate in a patient's collaborative drug therapy
40 management;

41 c. specifies the functions and responsibilities the pharmacist will be
42 performing;

43 d. is available at the practice sites of the pharmacist and physician
44 and made available at each site to the patient;

45 e. is initiated and utilized at the sole discretion of the physician for

- 1 a specific patient;
2 f. may be terminated at any time by either party by written
3 documentation;
4 g. establishes when physician notification is required, the physician
5 chart update interval, and an appropriate time frame within which the
6 pharmacist must notify the physician of any change in dose, duration
7 or frequency of medication prescribed; ⁴[and] ⁴
8 h. remains in effect for a period not to exceed two years upon the
9 conclusion of which, or sooner, the parties shall review the protocol
10 and make a determination as to its renewal, modification or
11 termination ⁴; and
12 i. establish the means by which the patient will be advised of the
13 right to elect to participate in and withdraw from the collaborative
14 drug therapy management⁴ .¹
15
16 ¹23. a. Each collaborative drug therapy management shall be
17 between a single patient's specific physician and the patient's
18 pharmacist or ⁴[pharmacists] pharmacy ⁴and address that patient's
19 specific condition, disease or diseases.
20 b. ²[A] No² collaborative drug therapy management² [may] shall
21 include, ²[with] without² the prior consent of ⁴the patient and⁴ the
22 patient's physician who has signed the protocol, therapeutic
23 interchange ²[for the prescription drug originally prescribed for the
24 patient's specific condition, disease or diseases] at the time of
25 dispensing² , provided that written confirmation of this prior consent,
26 which may be by electronic means, shall be obtained pursuant to
27 record keeping guidelines to be established by ⁴regulation jointly
28 promulgated by⁴ the board ⁴and the State Board of Medical
29 Examiners⁴ .¹
30
31 ¹24. a. No pharmacist shall administer a prescription medication
32 directly to a patient without appropriate education or certification, as
33 determined by the board ⁴in accordance with the requirements set
34 forth in the rules jointly promulgated by the board and the State Board
35 of Medical Examiners⁴ . Such medication shall only be for the
36 treatment of a disease for which a nationally certified program is in
37 effect, or as determined by the board, and only if utilized for the
38 treatment of that disease for which the medication is prescribed or
39 indicated or for which the collaborative drug therapy management
40 permits.
41 b. Notwithstanding any law, rule or regulation to the contrary,
42 other than for pediatric immunizations, a pharmacist may administer
43 drugs in immunization programs and programs sponsored by
44 governmental agencies that are not patient specific ²provided the
45 pharmacist is appropriately educated and qualified, as determined by
46 the board² ⁴in accordance with the requirements set forth in the rules

1 jointly promulgated by the board and the State Board of Medical
2 Examiners⁴ .¹

3
4 ¹25. The provisions of this act regulating collaborative drug
5 therapy management shall not apply to any pharmacist practicing in a
6 hospital, provided that prescribing within these institutions takes place
7 under the guidance of a pharmacy and therapeutics committee in
8 accordance with procedures as determined by regulations⁴ [of] jointly
9 promulgated by⁴ the board⁴ and the State Board of Medical
10 Examiners⁴ .¹

11
12 ¹26. In addition to the provisions of section 8 of P.L.1978, c.73
13 (C.45:1-21), the board may refuse an application for examination or
14 may suspend or revoke the certificate of a licensed pharmacist upon
15 proof satisfactory to the board that such licensed pharmacist is guilty
16 of grossly unprofessional conduct and the following acts are hereby
17 declared to constitute grossly unprofessional conduct for the purpose
18 of this act:

19 a. Paying rebates or entering into an agreement for payment of
20 rebates to any physician, dentist or other person for the recommending
21 of the services of any person.

22 b. The providing or causing to be provided to a physician, dentist,
23 veterinarian or other person authorized to prescribe, prescription
24 blanks or forms bearing the pharmacist's or pharmacy's name, address
25 or other means of identification.

26 c. The claiming of professional superiority in the compounding or
27 filling of prescriptions or in any manner implying professional
28 superiority which may reduce public confidence in the ability,
29 character or integrity of other pharmacists.

30 d. Fostering the interest of one group of patients at the expense of
31 another which compromises the quality or extent of professional
32 services or facilities made available.

33 e. The distribution of premiums or rebates of any kind whatever in
34 connection with the sale of drugs and medications provided, however,
35 that trading stamps and similar devices shall not be considered to be
36 rebates for the purposes of this act and provided further that
37 discounts, premiums and rebates may be provided in connection with
38 the sale of drugs and medications to any person who is 60 years of age
39 or older.

40 f. Advertising of prescription drug prices in a manner inconsistent
41 with rules and regulations promulgated by the Director of the Division
42 of Consumer Affairs, except that no advertising of any drug or
43 substance shall be authorized unless the Commissioner of Health and
44 Senior Services shall have determined that the advertising is not
45 harmful to public health, safety and welfare.

46 ⁴g. Engaging in activities beyond the scope of a collaborative drug

1 therapy management agreement.⁴

2 Before a certificate shall be refused, suspended or revoked, the
3 accused person shall be furnished with a copy of the complaint and
4 given a hearing before the board. Any person whose certificate is so
5 suspended or revoked shall be deemed an unlicensed person during the
6 period of such suspension or revocation, and as those shall be subject
7 to the penalties prescribed in this act, but that person may, at the
8 discretion of the board, have his certificate reinstated at any time
9 without an examination, upon application to the board. Any person to
10 whom a certificate shall be denied by the board or whose certificate
11 shall be suspended or revoked by the board shall have the right to
12 review that action by appeal to the Appellate Division of the Superior
13 Court in lieu of prerogative writ.¹

14

15 ¹[21.] 27.¹ a. A pharmacist shall conduct a ⁴[prospective]⁴ drug
16 utilization review before each new ¹[prescription] medication¹ is
17 dispensed or delivered to a patient.

18 b. A pharmacist shall conduct a prospective drug utilization review
19 in accordance with the provisions of this section before refilling a
20 prescription ¹or medication order¹ to the extent he deems appropriate
21 in his professional judgment.

22 c. A pharmacist shall exercise independent professional judgment
23 ⁴[in deciding] as to⁴ whether or not to dispense or refill a prescription
24 ¹or medication order .¹ In determining to dispense or refill a
25 prescription ¹or medication order¹, the decision of the pharmacist shall
26 not be arbitrary but shall be based on professional experience,
27 knowledge or available reference materials.

28

29 ¹[22.] 28.¹ ¹[a. A pharmacist shall offer to counsel any person
30 who presents a new prescription for filling. The offer to counsel may
31 be made in any manner the pharmacist deems appropriate in his
32 professional judgment, and shall include any one or a combination of
33 the following:

- 34 (1) Face-to-face communication with pharmacist;
35 (2) Face-to-face communication with ancillary personnel; or
36 (3) By telephone or other electronic methods.

37 For the purpose of Medicaid or other third-party reimbursement or
38 payment programs, any of the above methods, or a combination of
39 them, shall constitute an acceptable offer to provide counseling except
40 to the extent that this subsection is inconsistent with regulations
41 promulgated by the federal Health Care Financing Administration
42 pursuant to 42 U.S.C.s.1396r-8(g)(2)(A)(ii).

43 b. If, in the professional judgment of the pharmacist, it is
44 inappropriate to verbally make the offer to counsel, or if the patient is
45 not physically present in the pharmacy, the offer to counsel may be
46 made in a written communication.

1 c. A pharmacist may offer to counsel any person who receives a
2 refill prescription in accordance with the provisions of this section to
3 the extent he deems appropriate in his professional judgment.

4 d. If the offer to counsel is accepted, the pharmacist shall counsel
5 the person presenting the prescription to the extent the pharmacist
6 deems appropriate in his professional judgment. Counseling shall be
7 performed only by the pharmacist, or extern or intern under the
8 immediate supervision of the pharmacist, and may include the
9 following:

10 (1) The name and description of the medication;

11 (2) The dosage and dosage form, route of administration and
12 duration of drug therapy;

13 (3) Special directions and precautions for preparation,
14 administration and use by the patient;

15 (4) Common adverse or severe side effects or interactions and
16 therapeutic contraindications that may be encountered, including their
17 avoidance, and the action required if they occur;

18 (5) Techniques for self-monitoring drug therapy;

19 (6) Proper storage;

20 (7) Prescription refill information; and

21 (8) Action to be taken in the event of a missed dose.

22 e. Nothing in this section shall be construed as requiring a
23 pharmacist to provide counseling when the person presenting the
24 prescription fails to accept the pharmacist's offer to counsel. If the
25 prescription is filled for a person residing outside of the local
26 telephone calling area of the pharmacy, the pharmacist shall either
27 provide a toll-free telephone number or accept reasonable collect calls
28 from the person.] A pharmacist⁴ or his designee⁴ shall⁴ offer to⁴
29 provide counseling to any person who presents a new prescription in
30 a manner as determined pursuant to criteria established by the board.¹

31
32 ¹[23.] 29.¹ a. A patient profile system shall be maintained by all
33 pharmacies for persons for whom ¹[prescriptions] medications¹ are
34 dispensed. The patient profile record system shall enable the
35 dispensing pharmacist to identify previously dispensed medication at
36 the time a prescription is presented for dispensing.

37 b. The following information generated or transferred to the
38 individual pharmacy practice site shall be recorded in the patient
39 profile system:

40 (1) The ¹[full] family and the first¹ name of the person for whom
41 the medication is intended (the patient);

42 (2) The street address and telephone number of the patient;

43 (3) ¹[The] Indication of the¹ patient's age, birth date or age group
44 (infant, child, adult) and gender;

45 (4) The height, weight and other patient specific criteria for those
46 medications that are height or weight dose dependent;

1 (5) The original or refill date the medication is dispensed and the
2 initials of the dispensing pharmacist, if those initials and date are not
3 recorded on the original prescription or in any other record approved
4 by the board;

5 (6) The number or designation identifying the prescription;

6 (7) The practitioner's name;

7 (8) The name, strength and quantity of the drug dispensed;

8 (9) The individual history, if significant, including known allergies
9 and drug reactions, known diagnosed disease states and a
10 comprehensive list of medications and relevant devices; and

11 (10) Any additional comments relevant to the patient's drug use,
12 ⁴[and] which⁴ may include any failure to accept the pharmacist's offer
13 to counsel.

14 c. The information obtained shall be recorded in the patient's
15 manual or electronic profile, or in the prescription signature log, or in
16 any other system of records, and may be considered by the pharmacist
17 in the exercise of his professional judgment concerning both the offer
18 to counsel and content of counseling. The absence of any record of a
19 failure to accept the pharmacist's offer to counsel shall be presumed to
20 signify that the offer was accepted and that the counseling was
21 provided.

22
23 ¹[24.] 30.¹ a. All pharmacy practice sites ⁴[,]⁴ in ²[or out of]²
24 this State ⁴[or another state]⁴, which engage in the practice of
25 pharmacy in the State of New Jersey, shall be issued a permit by the
26 board, and shall annually renew their permit with the board. If
27 operations are conducted at more than one location, each location
28 shall be issued a permit by the board ¹for the dispensing of medicine¹.

29 b. The board may determine by rule or regulation the permit
30 classifications of all pharmacy practice sites issued a permit under this
31 act, and establish minimum standards for pharmacy practice sites.

32 c. The board shall establish by rule or regulation the criteria which
33 each site shall meet to qualify for a permit in each classification. The
34 board may issue permits with varying restrictions to pharmacy practice
35 sites if the board deems it necessary.

36 d. Each holder of a pharmacy practice site permit shall ensure that
37 a licensed pharmacist be immediately available on the premises to
38 provide pharmacy services at all times the pharmacy practice site is
39 open.

40 e. Each pharmacy practice site shall have a pharmacist-in-charge.
41 The pharmacist-in-charge and the owner of a pharmacy practice site
42 shall be responsible for any violation of any laws or regulations
43 pertaining to the practice of pharmacy.

44 f. The board may enter into agreements with other states or with
45 third parties for the purpose of exchanging information concerning the
46 granting of permits and the inspection of pharmacy practice sites
47 located in this State and those located outside this State.

1 g. The board may deny, suspend, revoke, restrict or refuse to
2 renew a permit for a pharmacy practice site that does not comply with
3 the provisions of this act ⁴or any rule or regulation promulgated
4 pursuant to this act⁴.

5 ¹[25.] 31.¹ a. The board shall specify by rule or regulation the
6 permit application procedures to be followed, including, but not
7 limited to, the specification of forms to be used, the time and place the
8 application is to be made and the fees to be charged.

9 b. Applicants for a permit to operate a pharmacy practice site
10 within this State shall file with the board a verified application
11 containing the information that the board requires of the applicant
12 relative to the qualifications for the specific permit.

13 c. The board shall specify, by rule or regulation, minimum
14 standards for any pharmacy practice site ⁴[that has employees or
15 personnel engaged in the practice of pharmacy that routinely serves
16 New Jersey residents] within this State⁴. Pharmacy practice sites
17 located in New Jersey shall be operated at all times under the
18 immediate supervision of a pharmacist licensed to practice in this
19 State.

20 d. Permits issued by the board pursuant to this act shall not be
21 transferable or assignable ¹without the approval of the board¹.

22
23 ¹[26.] 32.¹ No person shall carry on, conduct or transact business
24 under a name which contains as a part thereof the words "pharmacist,"
25 "pharmacy," "apothecary," "apothecary shop," "druggist," "drug" or
26 any word or words of similar or like import, or in any manner by
27 advertisement, circular, poster, sign or otherwise describe or refer to
28 the place of business by the terms "pharmacy," "apothecary,"
29 "apothecary shop," "chemist's shop," "drug store," "drugs" or any
30 word or words of similar or like import unless the place of business is
31 a currently licensed pharmacy practice site operated or managed at all
32 ¹[time] times¹ by a pharmacist.

33
34 ¹[27.] 33.¹ This act shall not prohibit, restrict or otherwise
35 interfere with the sale of non-prescription drugs and devices at places
36 other than a pharmacy practice site or by persons in this State who are
37 not licensed pharmacists.

38
39 ¹[28.] 34.¹ ³[2a.]²³ Any pharmacy ⁴[practice site] ⁴located
40 ²[outside this State] in another state² which ships, mails, distributes
41 or delivers in any manner, legend drugs or devices pursuant to a
42 prescription into this State, shall ⁴[have a permit for a pharmacy
43 practice site issued by] register with the board and provide⁴ the board
44 ⁴with the following information:

45 (1) The location, names and titles of all principal corporate officers

1 of the pharmacy. A report containing this information shall be made
 2 on an annual basis and within 30 days after any change of office or
 3 corporate officer; and

4 (2) That it complies with all lawful directions and requests for
 5 information from the regulatory or licensing agency of the state in
 6 which it is licensed as well as with all requests for information made
 7 by the board pursuant to this section. As a prerequisite to registering
 8 with the board, the pharmacy shall submit a copy of the most recent
 9 inspection report resulting from an inspection conducted by the
 10 regulatory or licensing agency of the state in which it is located.

11 The annual registration fee shall be established by the board and
 12 shall not exceed \$500 annually.

13 Any pharmacy subject to this section shall, during its regular hours
 14 of operation, but not less than six days per week, and for a minimum
 15 of 40 hours per week, provide a toll-free telephone service to facilitate
 16 communication between patients in this State and a pharmacist at a
 17 pharmacy who has access to the patient's records. This toll-free
 18 number shall be disclosed on a label affixed to each container of drugs
 19 dispensed to patients in this State⁴.

20 ³[²b. Any person located outside the United States shall be
 21 prohibited from shipping, mailing, distributing or delivering in any
 22 manner to any person in this State legend drugs or devices approved
 23 by the federal Food and Drug Administration and available in the
 24 United States pursuant to a prescription.²]³

25

26 ¹[29.] 35.¹ a. All licensed pharmacy practice sites shall report to
 27 the board the occurrences of any of the following:

28 (1) Closing of the pharmacy practice site;

29 (2) Change of ownership, location, interior site design ¹permit
 30 classification¹ or pharmacist-in-charge of the pharmacy practice site;

31 (3) Any significant theft or loss of legend drugs or devices;

32 (4) Disasters, accidents, any theft, destruction or loss of records
 33 required to be maintained by State or federal law;

34 (5) Any pharmacy malpractice liability insurance claim settlement,
 35 judgment or arbitration award in excess of \$10,000 to which an owner,
 36 an employee of, or the pharmacy practice site itself is a party; and

37 (6) Any and all other matters and occurrences as the board may
 38 require by rule or regulation.

39 b. The manner, time and content of the notification shall be
 40 prescribed by rule or regulation by the board.

41

42 ¹[30.] 36.¹ a. No pharmacy practice site shall operate until it has
 43 been issued a permit by the board.

44 b. The board may suspend, revoke, deny, restrict or refuse to
 45 renew the permit of any pharmacy practice site on any of the following
 46 grounds:

- 1 (1) Findings by the board that any conduct of the permit holder or
2 applicant is violative of any federal, State or local laws or regulations
3 relating to the practice of pharmacy;
- 4 (2) A conviction of the permit holder or applicant under federal,
5 State or local laws for a crime of moral turpitude or a crime that
6 relates adversely to the practice of pharmacy;
- 7 (3) Materially false or fraudulent information contained within any
8 application made to the board or in any application relating to drug or
9 device prescribing, dispensing or administration;
- 10 (4) Suspension or revocation by federal, State or local government
11 of any license or permit relating to the practice of pharmacy currently
12 or previously held by the applicant or permit holder;
- 13 (5) Utilizing a permit to obtain remuneration by fraud,
14 misrepresentation or deception;
- 15 (6) Dealing with drugs or devices that are known or should have
16 been known as stolen drugs or devices;
- 17 (7) Purchasing or receiving of a drug or device by a permit holder
18 or for use at a pharmacy practice site from a source that is not licensed
19 under the laws of the State, except where otherwise provided;
- 20 (8) Intensive and ongoing failure to provide additional personnel,
21 automation and technology as is necessary to ensure that the licensed
22 pharmacist on duty has sufficient time to utilize the professional's
23 knowledge and training and to competently perform the functions of
24 a licensed pharmacist as required by law;
- 25 (9) Violation of any of the provisions of the "New Jersey
26 Controlled Dangerous Substance Act," P.L.1970, c.226 (C.24:21-1 et
27 seq.) by the applicant, permit holder or occurring at the pharmacy
28 practice site; or
- 29 (10) Violations of any of the provisions of P.L.1978, c.73 (C.45:1-
30 14 et seq.) by the applicant, permit holder or occurring at the
31 pharmacy practice site.
- 32 c. Reinstatement of a permit that has been suspended or restricted
33 by the board may be granted in accordance with the procedures
34 specified by ⁴[section 6 of P.L.1999, c.403 (C.45:1-7.2)] the board⁴.
35
- 36 ¹[31.] 37.¹ ⁴[Confidential information is declared to be privileged
37 and shall not be released except to the patient or, as the patient
38 consents, to those practitioners, other authorized health care
39 professionals and other pharmacists if in the pharmacist's professional
40 judgement, the release is necessary to protect the patient's health and
41 well being; to persons or governmental agencies authorized by law to
42 receive such confidential information, regardless of]⁴ ¹[the medium
43 in which it is received or preserved] ⁴[the form of paper, preserved on
44 microfilm, or is stored by electronic means¹; or to the payor or payor's
45 agent] Pharmacists and pharmacies shall comply with the provisions
46 of the federal Standards of Practice of Individually Identifiable Health

1 Information, 45 C.F.R. Parts 160 and 164⁴.

2

3 ¹[32.] 38.¹ A person who in good faith and without malice
4 provides to the board any information concerning any act by a
5 pharmacist licensed by the board which the person has reasonable
6 cause to believe involves misconduct that may be subject to
7 disciplinary action by the board, or any information relating to such
8 conduct requested by the board in the exercise of its statutory
9 responsibilities or which may be required by statute, shall not be liable
10 for civil damages in any cause of action arising out of the provision of
11 such information or services.

12

13 ¹[33.] 39.¹ a. Any person who is licensed in this State as a
14 pharmacist on the effective date of this act may continue to practice
15 under his current license until its expiration, and to obtain a license
16 under this act without examination upon payment of a fee.

17 b. Any site with a permit in this State as a pharmacy practice site
18 on the effective date of this act may continue to operate under its
19 current permit until its expiration.

20

21 ¹[34.] 40.¹ This act shall not affect the orders, rules and
22 regulations regarding the practice of pharmacy made or promulgated
23 by the board created pursuant to R.S.45:14-1 et seq. prior to the
24 effective date of this act.

25

26 ¹41. a. Pharmacy technicians may assist a licensed pharmacist in
27 performing the following tasks:

28 (1) Retrieval of prescription files, patient files and profiles and other
29 records, as determined by the board, pertaining to the practice of
30 pharmacy;

31 (2) Data entry;

32 (3) Label preparation; and

33 (4) Counting, weighing, measuring, pouring and compounding of
34 prescription medication or stock legend drugs and controlled
35 substances⁴, including the filling of an automated medication system⁴.

36 b. Pharmacy technicians may accept authorization from a patient
37 for a prescription refill, or from a physician or the physician's agent for
38 a prescription renewal, provided that the prescription remains
39 unchanged. As used in this section, "prescription refill" means the
40 dispensing of medications pursuant to a prescriber's authorization
41 provided on the original prescription and "prescription renewal" means
42 the dispensing of medications pursuant to a practitioner's authorization
43 to fill an existing prescription that has no refills remaining.

44 c. Pharmacy technicians shall not:

45 (1) Receive new verbal prescriptions;

46 (2) Interpret a prescription or medication order for therapeutic

- 1 acceptability and appropriateness;
2 (3) Verify dosage and directions;
3 (4) Engage in prospective drug review;
4 (5) Provide patient counseling;
5 (6) Monitor prescription usage;
6 (7) Override computer alerts without first notifying the pharmacist;
7 (8) Transfer prescriptions from one pharmacy to another pharmacy;
8 or
9 (9) Violate patient confidentiality.
- 10 d. Except as provided in subsection e. of this section, a pharmacist
11 shall not supervise more than two pharmacy technicians.
- 12 e. A pharmacy that wishes to employ a licensed pharmacist to
13 pharmacy technician ratio greater than established in accordance with
14 subsection d. of this section, shall:
- 15 (1) Establish written job descriptions, task protocols and policies
16 and procedures that pertain to the duties performed by the pharmacy
17 technician;
- 18 (2) Ensure and document that each pharmacy technician pass the
19 National Pharmacy Technician Certification Examination ⁴ or a board
20 approved certification program⁴ and fulfill the requirements to
21 maintain this status, or complete a program which includes a testing
22 component and which has been approved by the board as satisfying the
23 criteria as set forth in subsection f. of this section;
- 24 (3) Ensure that each pharmacy technician is knowledgeable in the
25 established job descriptions, task protocols and policies and
26 procedures in the pharmacy setting in which the technician is to
27 perform his duties;
- 28 (4) Ensure that the duties assigned to any pharmacy technician do
29 not exceed the established job descriptions, task protocols and policies
30 and procedures;
- 31 (5) Ensure that each pharmacy technician receives in-service
32 training before the pharmacy technician assumes his responsibilities
33 and maintain documentation thereof;
- 34 (6) Require and maintain on site a signed patient confidentiality
35 statement from each technician;
- 36 (7) Provide immediate personal supervision; and
37 (8) Provide the board, upon request, with a copy of the established
38 job descriptions, task protocols and policies and procedures for all
39 pharmacy technician duties.
- 40 f. If the pharmacist to pharmacy technician ratio is greater than the
41 ratio established in accordance with the provisions of subsection d. of
42 this section, the pharmacy shall maintain a policy and procedure
43 manual with regard to pharmacy technicians, which shall include the
44 following:
- 45 (1) Supervision by a pharmacist;
46 (2) Confidentiality safeguards of patient information;

- 1 (3) Minimum qualifications;
- 2 (4) Documentation of in-service education or ongoing training and
3 demonstration of competency, specific to practice site and job
4 function;
- 5 (5) General duties and responsibilities of pharmacy technicians;
- 6 (6) Retrieval of prescription files, patient files, patient profile
7 information and other records pertaining to the practice of pharmacy;
- 8 (7) ⁴[All functions] Functions⁴ related to prescription processing;
- 9 (8) ⁴[All functions] Functions⁴ related to prescription legend drug
10 and controlled dangerous substance ordering and inventory control;
- 11 (9) Prescription refill and renewal authorization;
- 12 (10) Procedures dealing with documentation and records required
13 for controlled dangerous substance and prescription legend drugs;
- 14 (11) Procedures dealing with medication errors ⁴[, including
15 classification of medication errors]⁴;
- 16 (12) Pharmacy technician functions related to automated systems;
- 17 (13) Functions that may not be performed by pharmacy technicians;
18 and
- 19 (14) A form signed by the pharmacy technician which verifies that
20 the manual has been reviewed by the technician.
- 21 g. The pharmacist in charge shall review the policy and procedure
22 manual at least every two years and, if necessary, amend the manual
23 as needed. Documentation of the review shall be made available to the
24 board upon request.
- 25 h. Pharmacy technicians shall wear an identification tag, which shall
26 include at least their first name, the first initial of their last name and
27 title.
- 28 i. On pharmacy permit renewal applications, the pharmacy shall list
29 the name and address of all pharmacy technicians which it currently
30 employs.
- 31 j. When pharmacy technicians are engaged in any activities
32 permitted in accordance with the provisions of this section, the
33 licensed pharmacists on site shall be responsible for these activities.¹
34
- 35 ¹[35.] 42.¹ R.S.45:14-1 et seq.; section 6 of P.L.1970, c.331
36 (C.45:14-3.1); section 4 of P.L.1991, c.304 (C.45:14-3.2) P.L.1946,
37 c.177 (C.45:14-7.2); P.L.1948, c.50 (C45:14-7.3); P.L.1969, c.164
38 (C.45:14-8.1); P.L.1944, c.132 (C.45:14-11.1); P.L.1995, c.79
39 (C.45:14-11.11 through 45:14-11.16), section 3 of P.L.1965, c.120
40 (C.45:14-12.1); P.L.1996, c.154 (C.45:14-14.1 through 45:14-14.6);
41 P.L.1993, c.120 (C.45:14-15.1 through 45:14-15.4); section 2 of
42 P.L.1953, c.329 (C.45:14-16.1); sections 1 and 2 of P.L.1949, c.93
43 (C.45:14-26.1 and 45:14-26.2); and P.L.1948, c.105 (C.45:14-36.1
44 through 45:14-36.4) are repealed.
45
- 46 ¹[36.] 43.¹ This act shall take effect ¹[on the 180th day following

1 enactment, except that section 4 shall take effect] ^{1 4} on the 180th day
2 following enactment, except that section 4 shall take effect⁴
3 immediately.

4

5

6

7

8 Enacts new law to regulate and license pharmacists.

ASSEMBLY, No. 570

STATE OF NEW JERSEY 210th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2002 SESSION

Sponsored by:

Assemblyman ANTHONY IMPREVEDUTO

District 32 (Bergen and Hudson)

Assemblywoman JOAN M. QUIGLEY

District 32 (Bergen and Hudson)

SYNOPSIS

Enacts new law to regulate and license pharmacists.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



A570 IMPREVEDUTO, QUIGLEY

2

1 AN ACT regulating and licensing pharmacists and repealing various
2 parts of the statutory law.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. a. The act shall be known and may be cited as the "New Jersey
8 Pharmacy Practice Act."

9 b. The practice of pharmacy in this State is declared a health care
10 professional practice affecting the public health, safety and welfare and
11 is subject to regulation and control in the public interest. It is further
12 declared to be a matter of public interest and concern that the practice
13 of pharmacy merits and receives the confidence of the public and that
14 only qualified persons be permitted to engage in the practice of
15 pharmacy in this State. This act shall be liberally construed to carry
16 out these objectives and purposes.

17 c. It is the purpose of this act to promote, preserve and protect the
18 public health, safety and welfare by and through the effective control
19 and regulation of the practice of pharmacy, the licensure of
20 pharmacists and the permitting, control and regulation of all pharmacy
21 practice sites, in or out of this State, that engage in the practice of
22 pharmacy.

23
24 2. As used in this act:

25 "Administer" means the direct application of a drug to the body of
26 a patient or research subject by subcutaneous, intramuscular or
27 intradermal injection, inhalation, ingestion or any other means by a
28 pharmacist engaged in collaborative practice or in accordance with
29 regulations of the board.

30 "Automated medication device" means a discrete unit that performs
31 specific drug dispensing operations.

32 "Automated medication system" means any process that performs
33 operations or activities, other than compounding or administration,
34 relative to the storage, packaging, dispensing and distribution of
35 medications and which collects, controls and maintains all transaction
36 information.

37 "Board of Pharmacy" or "board" means the New Jersey State Board
38 of Pharmacy.

39 "Certification" means a certification awarded by a recognized non-
40 government specialty organization to signify that a pharmacist has met
41 predetermined qualifications and to signify to the public that the
42 pharmacist is competent to practice in the designated specialty.

43 "Collaborative drug therapy management" means a written protocol
44 between a patient's physician who is treating the patient for a specific
45 disease and a pharmacist for cooperative management of a patient's
46 drug, biological and device-related health care needs, which may

1 include, but not be limited to: collecting, analyzing and monitoring of
2 patient data; ordering of laboratory tests; ordering or performing of
3 clinical tests; prescribing, initiating, modifying, continuing or
4 discontinuing drug or device therapy; and therapeutic drug monitoring
5 with appropriate modification to dose, dosage regimen, dosage forms
6 or route of administration.

7 "Compounding" means the preparation, mixing, assembling,
8 packaging or labeling of a drug or device as the result of a
9 practitioner's prescription or initiative based on the relationship of the
10 practitioner or patient with the pharmacist in the course of
11 professional practice or for the purpose of, or incident to, research,
12 teaching or chemical analysis and not for sale or dispensing.
13 Compounding also includes the preparation of drugs or devices in
14 anticipation of prescription drug orders based on routine, regularly
15 observed prescribing patterns.

16 "Confidential information" means information that is identifiable as
17 to the patient involved that a pharmacist accesses, transmits or
18 maintains in a patient's record or which is communicated to or by the
19 patient as part of patient counseling.

20 "Credentialing" means the process by which an approved academic
21 institution awards a certificate to signify that the credentialed
22 pharmacist has completed the required courses, examinations or both,
23 that indicate advanced knowledge of a particular area of pharmacy.

24 "Deliver" or "delivery" means the actual constructive or attempted
25 transfer of a drug or device from one person to another, whether or
26 not for consideration.

27 "Device" means an instrument, apparatus, implement, machine,
28 contrivance, implant or other similar or related article, including any
29 component part or accessory, which is required under federal law to
30 bear the label "RX Only."

31 "Dispense" or "dispensing" means the procedure entailing the
32 interpretation of a practitioner's prescription order for a drug,
33 biological or device, and pursuant to that order the proper selection,
34 measuring, compounding, labeling and packaging in a proper container
35 for subsequent administration to, or use by, a patient.

36 "Drug or medication" means articles recognized as drugs in any
37 official compendium, or supplement thereto, designated from time to
38 time by the board for use in the diagnosis, cure, mitigation, treatment
39 or prevention of disease in humans or other animals; articles intended
40 for use in the diagnosis, cure, mitigation, treatment or prevention of
41 disease in humans or other animals; articles intended to affect the
42 structure or any function of the body of humans or other animals,
43 except that a food, dietary ingredient or dietary supplement, as those
44 terms are defined in 21 U.S.C.s.321, is not a drug solely because the
45 label or the labeling contains such a claim; and articles intended for use
46 as a component of and articles specified in this definition of "drug or

1 medication."

2 "Drug utilization review" includes, but is not limited to, the
3 following activities:

4 (1) Evaluation of prescription drug orders and patient records for
5 known allergies, rational therapy-contraindications, appropriate dose
6 and route of administration and appropriate directions for use;

7 (2) Evaluation of prescription drug orders and patient records for
8 duplication of therapy;

9 (3) Evaluation of prescription drug orders and patient records for
10 interactions between drug-drug, drug-food, drug-disease and adverse
11 drug reactions; and

12 (4) Evaluation of prescription drug orders and patient records for
13 proper utilization, including over- or under-utilization, and optimum
14 therapeutic outcomes.

15 "Extern" means any person who is in the fifth or sixth year of
16 college or the third or fourth professional year, at an accredited school
17 or college of pharmacy approved by the board, who is assigned to a
18 training site for the purpose of acquiring accredited practical
19 experience under the supervision of the school or college at which the
20 person is enrolled.

21 "Immediate supervision" means a level of control which assures that
22 the pharmacist is physically present at the pharmacy practice site and
23 has the responsibility for the accuracy and safety with respect to the
24 actions of pharmacy technicians, interns and externs.

25 "Intern" means any person who has graduated from an accredited
26 school or college of pharmacy approved by the board, or if a foreign
27 pharmacy graduate, any person who has met all of the requirements of
28 the board, and who is being trained by an approved preceptor for the
29 purpose of acquiring accredited practical experience and who has first
30 registered for that purpose with the board.

31 "Labeling" means the process of preparing and affixing a label to
32 any drug container, exclusive however, of the labeling by a
33 manufacturer, packer or distributor of a non-prescription drug or
34 commercially packaged legend drug or device.

35 "Licensed or permitted non-resident pharmacy" means a pharmacy
36 located outside this State that solicits, advertises, ships, mails or
37 delivers drugs pursuant to a valid prescription into this State.

38 "Licensure" means the process by which the board grants
39 permission to an individual to engage in the practice of pharmacy upon
40 finding that the applicant has attained the degree of competency
41 necessary to ensure that the public health, safety and welfare will be
42 protected.

43 "Medication error" means a preventable event that may cause or
44 lead to inappropriate use of a medication or patient harm while the
45 medication is in the control of the practitioner, patient or consumer.

46 "Medication order" means a prescription for a specific patient in an

1 institutional setting.

2 "Non-prescription drug or device" means a drug or device which
3 may be obtained without a prescription and which is labeled for
4 consumer use in accordance with the requirements of the laws and
5 rules of this State and the federal government.

6 "Permit" means the authorization granted by the board to a site to
7 engage in the practice of pharmacy.

8 "Person" means an individual, corporation, partnership, association
9 or any other legal entity including government.

10 "Pharmaceutical care" means the provision by a pharmacist of drug
11 therapy review and other related patient care services intended to
12 achieve positive outcomes related to the treatment, cure or prevention
13 of a disease; control, elimination or reduction of a patient's symptoms;
14 or arresting or slowing of a disease process as defined by the rules and
15 regulations of the board.

16 "Pharmacist" means an individual currently licensed by this State to
17 engage in the practice of pharmacy.

18 "Pharmacist-in-charge" means a pharmacist who accepts
19 responsibility for the operation of a pharmacy practice site in
20 conformance with all laws and rules pertinent to the practice of
21 pharmacy and the distribution of drugs.

22 "Pharmacist in collaborative practice" means a pharmacist engaged
23 in the collaborative drug therapy management of a patient's drug,
24 biological and device-relating health care needs pursuant to a written
25 protocol, in collaboration with a licensed physician and in accordance
26 with the board's regulations.

27 "Pharmacy practice site" means any place in or outside of this State
28 where drugs are dispensed or pharmaceutical care is provided by a
29 licensed pharmacist.

30 "Pharmacy technician" means an individual working in a pharmacy
31 practice site who, under the immediate supervision of a pharmacist,
32 assists in pharmacy activities permitted by the rules and regulations of
33 the board that do not require the professional judgment of a
34 pharmacist.

35 "Practice of pharmacy" means a health care service by a pharmacist
36 that includes, but is not limited to: compounding, dispensing and
37 labeling of drugs, biologicals, radio pharmaceuticals or devices;
38 overseeing automated medication systems; interpreting and evaluating
39 prescriptions; administering and distributing drugs, biologicals and
40 devices; maintaining prescription drug records; advising and consulting
41 on the therapeutic values, content, hazards and uses of drugs,
42 biologicals and devices; managing and monitoring drug therapy;
43 collecting, analyzing and monitoring patient data; performing drug
44 utilization reviews; storing prescription drugs and devices; supervising
45 technicians, interns and externs; and such other acts, services,
46 operations or transactions necessary, or incidental to, providing

1 pharmaceutical care and education. In accordance with written
2 guidelines or protocols established with a licensed physician, the
3 "practice of pharmacy" also includes: initiating, prescribing, modifying,
4 continuing or discontinuing drug or device therapy; collaborative drug
5 therapy management; ordering of laboratory tests; and ordering and
6 performance of clinical tests.

7 "Practitioner" means an individual currently licensed, registered or
8 otherwise authorized by the jurisdiction in which the individual
9 practices to administer or prescribe drugs in the course of professional
10 practice.

11 "Preceptor" means an individual who is a pharmacist, meets the
12 qualifications under the rules and regulations of the board, and
13 participates in the instructional training of pharmacy interns and
14 externs.

15 "Prescription" means a lawful order of a practitioner for a drug, a
16 device or diagnostic agent for a specific patient.

17 "Prescription drug" or "legend drug" means a drug which, under
18 federal law, is required to be labeled prior to being delivered to the
19 pharmacist, with either of the following statements: "Rx Only" or
20 "Caution: Federal law restricts this drug to use by, or on the order of,
21 a licensed veterinarian" or is required by any applicable federal or state
22 law, rule or regulation to be dispensed pursuant to a prescription drug
23 order or is restricted to use by a practitioner only.

24 "Registration" means the process of making a list or being enrolled
25 in an existing list.

26

27 3. The board shall enforce the provisions of this act. The board
28 shall have all of the duties, powers and authority specifically granted
29 by or necessary for the enforcement of this act, as well as such other
30 duties, powers and authority as it may be granted from time to time by
31 applicable law.

32

33 4. a. The board shall consist of eleven members, two of whom
34 shall be public members and one of whom shall be a state executive
35 department member appointed pursuant to the provisions of P.L.1971,
36 c.60 (C.45:1-2.1 et seq.). Each of the remaining eight members shall
37 be pharmacists. Each pharmacist member shall have at least five years
38 of experience in the practice of pharmacy in this State after licensure,
39 and shall at the time of appointment and throughout their tenure: be
40 currently licensed and in good standing to engage in the practice of
41 pharmacy in this State, and be actively engaged in the practice of
42 pharmacy in this State.

43 b. The Governor shall appoint the members of the board. Every
44 state professional pharmacy association may send to the Governor the
45 names of pharmacists having the qualifications required by this section,
46 whom the Governor may appoint to fill any vacancy occurring in the

1 board. In appointing members to the board to fill vacancies of
2 members who engage in the practice of pharmacy, the Governor shall
3 appoint members so that the membership of the board includes, at all
4 times, at least one pharmacist employed by a chain drug retailer who
5 owns or operates seven or more pharmacy practice sites, one
6 pharmacist who is employed by a health care system and one
7 pharmacist who owns a pharmacy practice site in this State.

8 c. Except for the members first appointed, members of the board
9 shall be appointed for a term of five years, except that members of the
10 board who are appointed to fill vacancies which occur prior to the
11 expiration of a former member's full term shall serve the unexpired
12 portion of that term. The terms of the members of the board shall be
13 staggered, so that the terms of no more than three members shall
14 expire in any year. Each member shall serve until a successor is
15 appointed and qualified. The present members of the board appointed
16 pursuant to R.S.45:14-1 et seq. shall serve the balance of their terms.
17 Any present board member appointed initially for a term of less than
18 five years shall be eligible to serve for two additional full terms. No
19 member of the board shall serve more than two consecutive full terms.
20 The completion of the unexpired portion of a full term shall not
21 constitute a full term for purposes of this subsection.

22 d. The Governor may remove a member of the board after a
23 hearing for misconduct, incompetency, neglect of duty or for any other
24 sufficient cause.

25
26 5. a. The board shall elect from its members a president and other
27 officers that it deems appropriate and necessary to the conduct of its
28 business. The president of the board shall preside at all meetings of
29 the board and shall be responsible for the performance of all of the
30 duties and functions of the board required or permitted by this act.
31 Each additional officer elected by the board shall perform those duties
32 normally associated with his position and those other duties assigned
33 from time to time by the board. Officers elected by the board shall
34 serve terms of one year commencing with the day of their election and
35 ending upon election of their successors and shall serve no more than
36 two consecutive full terms in each office to which they are elected.

37 b. The position of executive director shall be held by a pharmacist
38 licensed in the State of New Jersey. The executive director shall be
39 responsible for the performance of the administrative functions of the
40 board and those other duties that the board may direct.

41
42 6. Each member of the board shall receive compensation pursuant
43 to section 2 of P.L. 1977, c. 285 (C. 45:1-2.5) of \$150 per day for
44 each day on which the member is engaged in performance of the
45 official duties of the board, and shall be reimbursed for all reasonable
46 and necessary expenses incurred in connection with the discharge of

1 those official duties.

2

3 7. The board shall meet at least once every month to transact its
4 business. The board shall meet at those additional times that it may
5 determine. Additional meetings may be called by the president of the
6 board or by two-thirds of the members of the board.

7

8 8. The board shall make, adopt, amend and repeal those rules and
9 regulations necessary for the proper administration and enforcement
10 of this act. Those rules and regulations shall be promulgated in
11 accordance with the "Administrative Procedure Act," P.L.1968, c.410
12 (C.52:14B-1 et seq.).

13

14 9. a. The board shall be responsible for the control and regulation
15 of the practice of pharmacy in this State including, but not limited to,
16 the following:

17 (1) The licensing by examination or by license transfer of
18 applicants who are qualified to engage in the practice of pharmacy
19 under the provisions of this act;

20 (2) The renewal of licenses to engage in the practice of pharmacy;

21 (3) The establishment and enforcement of professional standards
22 and rules of conduct of pharmacists engaged in the practice of
23 pharmacy;

24 (4) The establishment of requirements for pharmacists to engage
25 in collaborative practice;

26 (5) The establishment of requirements for pharmacists to
27 administer drugs directly to patients;

28 (6) The enforcement of those provisions of this act relating to the
29 conduct or competence of pharmacists practicing in this State, and the
30 suspension, revocation, failure to renew or restriction of licenses to
31 engage in the practice of pharmacy pursuant to the provisions of
32 P.L.1978, c.73 (C.45:1-14 et seq.);

33 (7) The regulation of pharmacy practiced through any
34 technological means;

35 (8) The regulation and control of automated medication systems
36 and automated medication devices within or outside of pharmacy
37 practice sites;

38 (9) The right to seize any drugs and devices found by the board to
39 constitute an imminent danger to the public health and welfare;

40 (10) The establishment of minimum specifications for record
41 keeping, prescription and profile record maintenance, pharmacy
42 practice sites including, but not limited to, the physical premises,
43 technical equipment, environment, supplies, personnel and procedures
44 for the storage, compounding and dispensing of drugs or devices, and
45 for the monitoring of drug therapy;

46 (11) The inspection of any pharmacy practice site at all reasonable

1 hours for the purpose of determining if any provisions of the laws
2 governing the legal distribution of drugs or devices or the practice of
3 pharmacy are being violated. The board, its officers, inspectors and
4 representatives shall cooperate with all agencies charged with the
5 enforcement of the laws of the United States, of this State, and of all
6 other states relating to drugs, devices and the practice of pharmacy;

7 (12) The inspection of prescription files and the prescription
8 records of a pharmacy and the removal from the files and taking
9 possession of any original prescription, providing that the authorized
10 agent removing or taking possession of an original prescription shall
11 place in the file from which it was removed a copy certified by that
12 person to be a true copy of the original prescription removed;
13 provided further, that the original copy shall be returned by the board
14 to the file from which it was removed after it has served the purpose
15 for which it was removed;

16 (13) The establishment of requirements for patient counseling,
17 patient profiles and drug utilization reviews; and

18 (14) The establishment of regulations to protect the health and
19 safety of pharmacy patients.

20 b. The board shall have those other duties, powers and authority
21 as may be necessary to the enforcement of this act and to the
22 enforcement of rules and regulations of the board, which may include,
23 but not limited to, the following:

24 (1) The determination and issuance of standards, recognition and
25 approval of degree programs of schools and colleges of pharmacy
26 whose graduates shall be eligible for licensure in this State, and the
27 specifications and enforcement of requirements for practical training,
28 including internships;

29 (2) The registration of externs, interns, pharmacy preceptors and
30 pharmacy technicians;

31 (3) The regulation of the training, qualifications and conduct of
32 applicants, externs, interns, pharmacy preceptors and pharmacy
33 technicians;

34 (4) The collection of professional demographic data;

35 (5) The joining with those professional organizations and
36 associations organized to promote the improvement of the standards
37 of the practice of pharmacy for the protection of the health and
38 welfare of the public or whose activities assist and facilitate the work
39 of the board;

40 (6) The establishment of a bill of rights for patients concerning the
41 health care services a patient may expect in regard to pharmaceutical
42 care;

43 (7) The engagement in activities to educate consumers, to assist
44 them in obtaining information necessary to make decisions about
45 medication issues;

46 (8) The assurance of ongoing professional competency of licensees

1 or registrants;

2 (9) The establishment of rules and regulations for extraordinary
3 emergency situations that interfere with the ability to practice under
4 the current rules and regulations;

5 (10) The establishment of guidelines for board approved pilot
6 programs. The guidelines shall be complied with to implement a
7 program that may not be presently acknowledged in this act or its rules
8 or regulations; and

9 (11) The assurance that any credentialing or certification of a
10 pharmacist is not misleading to the public.

11 c. (1) The board may place under seal all drugs, biologicals, radio
12 pharmaceuticals or devices that are owned by or in the possession,
13 custody or control of a licensee or permit holder at the time his license
14 or permit is suspended or revoked or at the time the board refused to
15 renew his license. Except as otherwise provided in this section, drugs,
16 biologicals, radio pharmaceuticals or devices that are sealed pursuant
17 to this paragraph shall not be disposed of until appeal rights under the
18 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.)
19 have expired, or an appeal filed pursuant to that act has been
20 determined. The court, involved in an appeal filed pursuant to the
21 "Administrative Procedure Act," may order the board, during the
22 pendency of the appeal, to sell sealed drugs, biologicals and radio
23 pharmaceuticals that are perishable. The proceeds of a sale shall be
24 deposited with the court.

25 (2) Notwithstanding any provisions of this act to the contrary,
26 whenever a duly authorized representative of the board finds, or has
27 probable cause to believe, that any drug or device is outdated,
28 adulterated or misbranded within the meaning of the "Federal Food,
29 Drug, and Cosmetic Act," 21 U.S.C.s.301 et seq., the representative
30 shall affix to that drug or device a tag or other appropriate marking
31 giving notice that the article is or is suspected of being outdated,
32 adulterated or misbranded, had been detained or embargoed, and
33 warning all persons not to remove or dispose of the article by sale or
34 otherwise until provision for removing or disposal is given by the
35 board, its agent or the court. No person shall remove or dispose of an
36 embargoed drug or device by sale or otherwise without the permission
37 of the board or its agent or, after summary proceedings have been
38 instituted, without permission of the court.

39 (3) When a drug or device detained or embargoed under paragraph
40 (2) of this subsection c. has been declared by the representative to be
41 outdated, adulterated or misbranded, the board shall, as soon as
42 practical thereafter, petition the judge of the court in which
43 jurisdiction the article is detained or embargoed for an order for
44 condemnation of that article. If the judge determines that this drug or
45 device so detained or embargoed is not adulterated, outdated or
46 misbranded, the board shall direct the immediate removal of the tag or

1 other marking.

2 (4) If the court finds that a detained or embargoed drug or device
3 is adulterated, outdated or misbranded, that drug or device, after entry
4 of the decree, shall be destroyed at the expense of the owner under the
5 supervision of a board representative and all court costs and fees,
6 storage and other proper expenses shall be borne by the owner of that
7 drug or device. When the outdated, adulteration or misbranding can
8 be corrected by proper labeling or processing of the drug or device,
9 the court, after entry of the decree and after the costs, fees and
10 expenses have been paid and a good and sufficient bond has been
11 posted, may direct that the drug or device be delivered to the owner
12 thereof for labeling or processing under the supervision of a board
13 representative. Expense of that supervision shall be paid by the owner.
14 The bond shall be returned to the owner of the drug or device on
15 representation to the court by the board that the drug or device is no
16 longer in violation of the embargo and the expense of supervision has
17 been paid.

18 d. Except as otherwise provided to the contrary, the board shall
19 exercise all of its duties, powers and authority in accordance with the
20 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
21 seq.).

22 e. The board shall annually report to the Governor and to all
23 interested parties upon the condition of pharmacy practice in the State,
24 which report shall embrace a detailed statement of the receipts and
25 expenditures of the board.

26

27 10. a. Except as otherwise provided in this act, it shall be unlawful
28 for any individual to engage in the practice of pharmacy unless
29 currently licensed to practice under the provisions of this act.

30 b. Practitioners authorized under the laws of this State to
31 compound drugs and to dispense drugs directly to their patients in the
32 practice of their respective professions shall meet the same storage,
33 handling, security, counseling and record keeping requirements for the
34 dispensing of drugs applicable to pharmacists.

35

36 11. To obtain a license to engage in the practice of pharmacy, the
37 applicant shall:

38 a. Have submitted a written application in the form prescribed by
39 the board;

40 b. Have attained the age of 18 years;

41 c. Be of good moral character;

42 d. Have graduated and received a professional degree from a
43 college or school of pharmacy that has been approved by the board;

44 e. Have completed an internship or other program that has been
45 approved by the board, or demonstrated to the board's satisfaction
46 experience in the practice of pharmacy which meets or exceeds the

1 minimum internship requirements of the board;

2 f. Have successfully passed an examination or examinations given
3 by the board; and

4 g. Have paid the fees specified by the board for the examination
5 and any related materials, and have paid for the issuance of the license.

6

7 12. a. The examination for licensure shall be given by the board at
8 least two times during each year. The board shall determine the
9 content and subject matter of each examination, and the place, time
10 and date of administration of the examination as defined by
11 regulations.

12 b. The examination shall be prepared to measure the competence
13 of the applicant to engage in the practice of pharmacy. The board may
14 employ, cooperate and contract with any organization or consultant in
15 the preparation and grading of an examination, but shall retain the sole
16 discretion and responsibility for determining which applicants have
17 successfully passed the examination.

18

19 13. a. All applicants for licensure by examination shall obtain
20 practical experience in the practice of pharmacy under terms and
21 conditions determined by the board.

22 b. The board may establish licensure requirements for interns and
23 standards for internship, or any other experiential program necessary
24 to qualify an applicant for the licensure examination, and shall also
25 determine the qualifications of preceptors used in practical experience
26 programs.

27

28 14. a. In order for a pharmacist currently licensed in another
29 jurisdiction to obtain a license as a pharmacist by license transfer in
30 this State, an applicant shall:

31 (1) Have submitted a written application in the form prescribed by
32 the board;

33 (2) Have attained the age of 18 years;

34 (3) Have good moral character;

35 (4) Have possessed at the time of initial licensure as a pharmacist
36 all the qualifications necessary to have been eligible for licensure at
37 that time in this State;

38 (5) Have engaged in the practice of pharmacy for a period of at
39 least 1,000 hours within the last two years or have met, immediately
40 prior to application, the internship requirements of this State within
41 the one-year period immediately preceding the date of application;

42 (6) Have presented to the board proof of initial licensure by
43 examination and proof that the license is in good standing;

44 (7) Have presented to the board proof that any other license
45 granted to the applicant by any other state has not been suspended,
46 revoked or otherwise restricted for any reason except nonrenewal or

1 for the failure to obtain the required continuing education credits in
2 any state where the applicant is currently licensed but not engaged in
3 the practice of pharmacy;

4 (8) Have paid the fees specified by the board; and

5 (9) Have graduated and received a professional degree from a
6 college or school of pharmacy approved by the board.

7 b. No applicant shall be eligible for license transfer unless the state
8 in which the applicant is originally licensed as a pharmacist granted
9 licensure according to substantially equivalent requirements as this
10 State at that time. The applicant shall also hold a current valid license
11 in a state that grants licensure transfer to pharmacists duly licensed by
12 examination in this State.

13

14 15. a. The board shall require each person registered as a
15 pharmacist, as a condition for biennial renewal certification, to
16 complete 30 credits of continuing pharmacy education during each
17 biennial period immediately preceding the date of renewal and submit
18 proof thereof to the board.

19 b. The board shall:

20 (1) Establish standards for continuing pharmacy education,
21 including the subject matter and content of courses of study, the
22 selection of instructors and the type of continuing education credits
23 required of a registered pharmacist as a condition of biennial
24 registration;

25 (2) Approve educational programs offering credit towards
26 continuing pharmacy education requirements; and

27 (3) Approve other equivalent educational programs, including, but
28 not limited to, home study courses, and establish procedures for the
29 issuance of credit upon satisfactory proof of the completion of these
30 programs. In the case of education courses and programs, each hour
31 of instruction shall be equivalent to one credit.

32 c. (1) The board shall only approve programs that are provided on
33 a nondiscriminatory basis. The board shall permit any pharmacy
34 association or organization offering a continuing pharmacy education
35 program approved by the board pursuant to subsection b. of this
36 section to impose a reasonable differential in registration fees for
37 courses upon registered pharmacists who are not members of that
38 pharmacy association or organization. The board may approve
39 programs held within or outside the State.

40 (2) In no event shall the board grant credits for, or approve as, a
41 component of a continuing education program:

42 (a) participation in a routine business portion of a meeting of a
43 pharmacy association or organization; or

44 (b) any presentation that is offered to sell a product or promote a
45 business enterprise.

46 d. (1) The board may, in its discretion, waive requirements for

1 continuing education on an individual basis for reasons of hardship,
2 such as illness or disability, retirement of the registration certificate,
3 or any other good cause.

4 (2) The board shall not require completion of continuing education
5 credits for an initial renewal of registration.

6 (3) If a pharmacist completes a number of continuing education
7 credit hours in excess of the number required by subsection a. of this
8 section, the board may allow, by rule or regulation, credits to be
9 carried over to satisfy the pharmacist's continuing education
10 requirement for the next biennial renewal period, but shall not be
11 applicable thereafter.

12
13 16. a. A practitioner practicing in this State shall use non-
14 reproducible, non-erasable safety paper New Jersey Prescription
15 Blanks bearing that practitioner's license number whenever the
16 practitioner issues prescriptions for controlled dangerous substances,
17 prescription legend drugs or other prescription items. The prescription
18 blanks shall be secured from a vendor approved by the Division of
19 Consumer Affairs in the Department of Law and Public Safety.

20 b. A licensed practitioner practicing in this State shall maintain a
21 record of the receipt of New Jersey Prescription Blanks. The
22 practitioner shall notify the Office of Drug Control in the Division of
23 Consumer Affairs as soon as possible but no later than 72 hours of
24 being made aware that any New Jersey Prescription Blank in the
25 practitioner's possession has been stolen. Upon receipt of notification,
26 the Office of Drug Control shall take appropriate action, including
27 notification to the Department of Human Services and the Attorney
28 General.

29
30 17. a. Prescriptions issued by a health care facility licensed
31 pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) shall be written on
32 non-reproducible, non-erasable safety paper New Jersey Prescription
33 Blanks. The prescription blanks shall be secured from a vendor
34 approved by the Division of Consumer Affairs in the Department of
35 Law and Public Safety. The New Jersey Prescription Blanks shall bear
36 the unique provider number assigned to that health care facility for the
37 issuing of prescriptions for controlled dangerous substances,
38 prescription legend drugs or other prescription items.

39 b. A health care facility shall maintain a record of the receipt of
40 New Jersey Prescription Blanks. The health care facility shall notify
41 the Office of Drug Control in the Division of Consumer Affairs as
42 soon as possible but no later than 72 hours of being made aware that
43 any New Jersey Prescription Blank in the facility's possession has been
44 stolen. Upon receipt of notification, the Office of Drug Control shall
45 take appropriate action including notification to the Department of
46 Human Services and the Attorney General.

1 18. A prescription issued by a practitioner or health care facility
2 shall not be filled by a pharmacist unless the prescription is issued on
3 a New Jersey Prescription Blank bearing the practitioner's license
4 number or the unique provider number assigned to a health care
5 facility.

6
7 19. a. Nothing contained in this act shall preclude a practitioner
8 from transmitting to a pharmacist by telephone or electronic means a
9 prescription, as otherwise authorized by law, if that practitioner
10 provides the practitioner's Drug Enforcement Administration
11 registration number or practitioner's license number, as appropriate, to
12 the pharmacist at the time the practitioner transmits the prescription.

13 b. No prescription for any narcotic drug, except as provided in
14 section 15 of P.L.1970, c.226 (C.24:21-15), shall be given or
15 transmitted to pharmacists, in any other manner, than in writing signed
16 by the practitioner giving or transmitting the same, nor shall such
17 prescription be renewed or refilled. The requirement in this subsection
18 that a prescription for any narcotic drug be given or transmitted to
19 pharmacists in writing signed by the practitioner, shall not apply to a
20 prescription for a Schedule II drug written for a long-term care facility
21 resident or hospital patient if that prescription is transmitted or
22 prepared in compliance with federal Drug Enforcement Administration
23 regulations 21 C.F.R. 1306.11(d), (e), (f) and (g).

24
25 20. The Division of Consumer Affairs in the Department of Law
26 and Public Safety shall establish the format for uniform, non-
27 reproducible, non-erasable safety paper prescription blanks, to be
28 known as New Jersey Prescription Blanks, which format shall include
29 an identifiable logo or symbol that will appear on all prescription
30 blanks. The division shall approve a sufficient number of vendors to
31 ensure production of an adequate supply of New Jersey Prescription
32 Blanks for practitioners and health care facilities statewide.

33
34 21. a. A pharmacist shall conduct a prospective drug utilization
35 review before each new prescription is dispensed or delivered to a
36 patient.

37 b. A pharmacist shall conduct a prospective drug utilization review
38 in accordance with the provisions of this section before refilling a
39 prescription to the extent he deems appropriate in his professional
40 judgment.

41 c. A pharmacist shall exercise independent professional judgment
42 in deciding whether or not to dispense or refill a prescription. In
43 determining to dispense or refill a prescription, the decision of the
44 pharmacist shall not be arbitrary but shall be based on professional
45 experience, knowledge or available reference materials.

1 22. a. A pharmacist shall offer to counsel any person who presents
2 a new prescription for filling. The offer to counsel may be made in any
3 manner the pharmacist deems appropriate in his professional judgment,
4 and shall include any one or a combination of the following:

- 5 (1) Face-to-face communication with pharmacist;
- 6 (2) Face-to-face communication with ancillary personnel; or
- 7 (3) By telephone or other electronic methods.

8 For the purpose of Medicaid or other third-party reimbursement or
9 payment programs, any of the above methods, or a combination of
10 them, shall constitute an acceptable offer to provide counseling except
11 to the extent this subsection is inconsistent with regulations
12 promulgated by the federal Health Care Financing Administration
13 pursuant to 42 U.S.C.s.1396r-8(g)(2)(A)(ii).

14 b. If, in the professional judgment of the pharmacist, it is
15 inappropriate to verbally make the offer to counsel, or if the patient is
16 not physically present in the pharmacy, the offer to counsel may be
17 made in a written communication.

18 c. A pharmacist may offer to counsel any person who receives a
19 refill prescription in accordance with the provisions of this section to
20 the extent he deems appropriate in his professional judgment.

21 d. If the offer to counsel is accepted, the pharmacist shall counsel
22 the person presenting the prescription to the extent the pharmacist
23 deems appropriate in his professional judgment. Counseling shall be
24 performed only by the pharmacist, or extern or intern under the
25 immediate supervision of the pharmacist, and may include the
26 following:

- 27 (1) The name and description of the medication;
- 28 (2) The dosage and dosage form, route of administration and
29 duration of drug therapy;
- 30 (3) Special directions and precautions for preparation,
31 administration and use by the patient;
- 32 (4) Common adverse or severe side effects or interactions and
33 therapeutic contraindications that may be encountered, including their
34 avoidance, and the action required if they occur;
- 35 (5) Techniques for self-monitoring drug therapy;
- 36 (6) Proper storage;
- 37 (7) Prescription refill information; and
- 38 (8) Action to be taken in the event of a missed dose.

39 e. Nothing in this section shall be construed as requiring a
40 pharmacist to provide counseling when the person presenting the
41 prescription fails to accept the pharmacist's offer to counsel. If the
42 prescription is filled for a person residing outside of the local
43 telephone calling area of the pharmacy, the pharmacist shall either
44 provide a toll-free telephone number or accept reasonable collect calls
45 from the person.

1 23. a. A patient profile system shall be maintained by all
2 pharmacies for persons for whom prescriptions are dispensed. The
3 patient profile record system shall enable the dispensing pharmacist to
4 identify previously dispensed medication at the time a prescription is
5 presented for dispensing.

6 b. The following information generated or transferred to the
7 individual pharmacy practice site shall be recorded in the patient
8 profile system:

9 (1) The full name of the person for whom the medication is
10 intended (the patient);

11 (2) The street address and telephone number of the patient;

12 (3) The patient's age, birth date or age group (infant, child, adult)
13 and gender;

14 (4) The height, weight and other patient specific criteria for those
15 medications that are height or weight dose dependent;

16 (5) The original or refill date the medication is dispensed and the
17 initials of the dispensing pharmacist, if those initials and date are not
18 recorded on the original prescription or in any other record approved
19 by the board;

20 (6) The number or designation identifying the prescription;

21 (7) The practitioner's name;

22 (8) The name, strength and quantity of the drug dispensed;

23 (9) The individual history, if significant, including known allergies
24 and drug reactions, known diagnosed disease states and a
25 comprehensive list of medications and relevant devices; and

26 (10) Any additional comments relevant to the patient's drug use,
27 and may include any failure to accept the pharmacist's offer to counsel.

28 c. The information obtained shall be recorded in the patient's
29 manual or electronic profile, or in the prescription signature log, or in
30 any other system of records, and may be considered by the pharmacist
31 in the exercise of his professional judgment concerning both the offer
32 to counsel and content of counseling. The absence of any record of a
33 failure to accept the pharmacist's offer to counsel shall be presumed to
34 signify that the offer was accepted and that the counseling was
35 provided.

36

37 24. a. All pharmacy practice sites, in or out of this State, which
38 engage in the practice of pharmacy in the State of New Jersey, shall be
39 issued a permit by the board, and shall annually renew their permit
40 with the board. If operations are conducted at more than one location,
41 each location shall be issued a permit by the board.

42 b. The board may determine by rule or regulation the permit
43 classifications of all pharmacy practice sites issued a permit under this
44 act, and establish minimum standards for pharmacy practice sites.

45 c. The board shall establish by rule or regulation the criteria which
46 each site shall meet to qualify for a permit in each classification. The

1 board may issue permits with varying restrictions to pharmacy practice
2 sites if the board deems it necessary.

3 d. Each holder of a pharmacy practice site permit shall ensure that
4 a licensed pharmacist be immediately available on the premises to
5 provide pharmacy services at all times the pharmacy practice site is
6 open.

7 e. Each pharmacy practice site shall have a pharmacist-in-charge.
8 The pharmacist-in-charge and the owner of a pharmacy practice site
9 shall be responsible for any violation of any laws or regulations
10 pertaining to the practice of pharmacy.

11 f. The board may enter into agreements with other states or with
12 third parties for the purpose of exchanging information concerning the
13 granting of permits and the inspection of pharmacy practice sites
14 located in this State and those located outside this State.

15 g. The board may deny, suspend, revoke, restrict or refuse to
16 renew a permit for a pharmacy practice site that does not comply with
17 the provisions of this act.

18

19 25. a. The board shall specify by rule or regulation the permit
20 application procedures to be followed, including, but not limited to,
21 the specification of forms to be used, the time and place the
22 application is to be made and the fees to be charged.

23 b. Applicants for a permit to operate a pharmacy practice site
24 within this State shall file with the board a verified application
25 containing the information that the board requires of the applicant
26 relative to the qualifications for the specific permit.

27 c. The board shall specify by rule or regulation, minimum standards
28 for any pharmacy practice site that has employees or personnel
29 engaged in the practice of pharmacy that routinely serves New Jersey
30 residents. Pharmacy practice sites located in New Jersey shall be
31 operated at all times under the immediate supervision of a pharmacist
32 licensed to practice in this State.

33 d. Permits issued by the board pursuant to this act shall not be
34 transferable or assignable.

35

36 26. No person shall carry on, conduct or transact business under
37 a name which contains as a part thereof the words "pharmacist,"
38 "pharmacy," "apothecary," "apothecary shop," "druggist," "drug" or
39 any word or words of similar or like import, or in any manner by
40 advertisement, circular, poster, sign or otherwise describe or refer to
41 the place of business by the terms "pharmacy," "apothecary,"
42 "apothecary shop," "chemist's shop," "drug store," "drugs" or any
43 word or words of similar or like import unless the place of business is
44 a currently licensed pharmacy practice site operated or managed at all
45 time by a pharmacist.

1 27. This act shall not prohibit, restrict or otherwise interfere with
2 the sale of non-prescription drugs and devices at places other than a
3 pharmacy practice site or by persons in this State who are not licensed
4 pharmacists.

5
6 28. Any pharmacy practice site located outside this State which
7 ships, mails, distributes or delivers in any manner, legend drugs or
8 devices pursuant to a prescription into this State, shall have a permit
9 for a pharmacy practice site issued by the board.

10
11 29. a. All licensed pharmacy practice sites shall report to the board
12 the occurrences of any of the following:

13 (1) Closing of the pharmacy practice site;

14 (2) Change of ownership, location, interior site design or
15 pharmacist-in-charge of the pharmacy practice site;

16 (3) Any significant theft or loss of legend drugs or devices;

17 (4) Disasters, accidents, any theft, destruction or loss of records
18 required to be maintained by State or federal law;

19 (5) Any pharmacy malpractice liability insurance claim settlement,
20 judgment or arbitration award in excess of \$10,000 to which an owner,
21 an employee of, or the pharmacy practice site itself is a party; and

22 (6) Any and all other matters and occurrences as the board may
23 require by rule or regulation.

24 b. The manner, time and content of the notification shall be
25 prescribed by rule or regulation by the board.

26
27 30. a. No pharmacy practice site shall operate until it has been
28 issued a permit by the board.

29 b. The board may suspend, revoke, deny, restrict or refuse to
30 renew the permit of any pharmacy practice site on any of the following
31 grounds:

32 (1) Findings by the board that any conduct of the permit holder or
33 applicant is violative of any federal, State or local laws or regulations
34 relating to the practice of pharmacy;

35 (2) A conviction of the permit holder or applicant under federal,
36 State or local laws for a crime of moral turpitude or a crime that
37 relates adversely to the practice of pharmacy;

38 (3) Materially false or fraudulent information contained within any
39 application made to the board or in any application relating to drug or
40 device prescribing, dispensing or administration;

41 (4) Suspension or revocation by federal, State or local government
42 of any license or permit relating to the practice of pharmacy currently
43 or previously held by the applicant or permit holder;

44 (5) Utilizing a permit to obtain remuneration by fraud,
45 misrepresentation or deception;

46 (6) Dealing with drugs or devices that are known or should have

1 been known as stolen drugs or devices;

2 (7) Purchasing or receiving of a drug or device by a permit holder
3 or for use at a pharmacy practice site from a source that is not licensed
4 under the laws of the State, except where otherwise provided;

5 (8) Intensive and ongoing failure to provide additional personnel,
6 automation and technology as is necessary to ensure that the licensed
7 pharmacist on duty has sufficient time to utilize the professional's
8 knowledge and training and to competently perform the functions of
9 a licensed pharmacist as required by law;

10 (9) Violation of any of the provisions of the "New Jersey
11 Controlled Dangerous Substance Act," P.L.1970, c.226 (C.24:21-1 et
12 seq.) by the applicant, permit holder or occurring at the pharmacy
13 practice site; or

14 (10) Violations of any of the provisions of P.L.1978, c.73 (C.45:1-
15 14 et seq.) by the applicant, permit holder or occurring at the
16 pharmacy practice site.

17 c. Reinstatement of a permit that has been suspended or restricted
18 by the board may be granted in accordance with the procedures
19 specified by section 6 of P.L.1999, c.403 (C.45:1-7.2).

20

21 31. Confidential information is declared to be privileged and shall
22 not be released except to the patient or, as the patient consents, to
23 those practitioners, other authorized health care professionals and
24 other pharmacists if in the pharmacist's professional judgement, the
25 release is necessary to protect the patient's health and well being; to
26 persons or governmental agencies authorized by law to receive such
27 confidential information, regardless of the medium in which it is
28 received or preserved; or to the payor or payor's agent.

29

30 32. A person who in good faith and without malice provides to the
31 board any information concerning any act by a pharmacist licensed by
32 the board which the person has reasonable cause to believe involves
33 misconduct that may be subject to disciplinary action by the board, or
34 any information relating to such conduct requested by the board in the
35 exercise of its statutory responsibilities or which may be required by
36 statute, shall not be liable for civil damages in any cause of action
37 arising out of the provision of such information or services.

38

39 33. a. Any person who is licensed in this State as a pharmacist on
40 the effective date of this act may continue to practice under his current
41 license until its expiration, and to obtain a license under this act
42 without examination upon payment of a fee.

43 b. Any site with a permit in this State as a pharmacy practice site
44 on the effective date of this act may continue to operate under its
45 current permit until its expiration.

1 34. This act shall not affect the orders, rules and regulations
2 regarding the practice of pharmacy made or promulgated by the board
3 created pursuant to R.S.45:14-1 et seq. prior to the effective date of
4 this act.

5
6 35. R.S.45:14-1 et seq.; P.L.1946, c.177 (C.45:14-7.2); P.L.1948,
7 c.50 (C45:14-7.3); P.L.1969, c.164 (C.45:14-8.1); P.L.1944, c.132
8 (C.45:14-11.1); P.L.1995, c.79 (C.45:14-11.11 through 45:14-11.16),
9 section 3 of P.L.1965, c.120 (C.45:14-12.1); P.L.1996, c.154
10 (C.45:14-14.1 through 45:14-14.6); P.L.1993, c.120 (C.45:14-15.1
11 through 45:14-15.4); section 2 of P.L.1953, c.329 (C.45:14-16.1);
12 sections 1 and 2 of P.L.1949, c.93 (C.45:14-26.1 and 45:14-26.2);
13 P.L.1948, c.105 (C.45:14-36.1 through 45:14-36.4); section 6 of
14 P.L.1970, c.331 (C.45:14-3.1); and section 4 of P.L.1991, c.304
15 (C.45:14-3.2) are repealed.

16
17 36. This act shall take effect on the 180th day following enactment,
18 except that section 4 shall take effect immediately.

19
20
21 STATEMENT

22
23 This bill enacts the "New Jersey Pharmacy Practice Act" and
24 repeals the current law providing for the regulation and licensure of
25 pharmacists.

26 The bill reenacts most of the provisions of the current law with
27 some changes and includes some new provisions, such as providing
28 that pharmacists may be engaged in the management of a patient's
29 drug, biological and device-relating health care needs pursuant to a
30 written protocol in collaboration with a licensed physician and
31 providing for the regulation of pharmacies located outside of this State
32 that solicit, advertise, ship, mail or deliver drugs pursuant to a valid
33 prescription into this State. The provisions of the current law
34 requiring utilization reviews, patient profiles and counseling and non-
35 reproducible, non-erasable safety paper New Jersey Prescription
36 Blanks are continued under the bill.

ASSEMBLY REGULATED PROFESSIONS AND
INDEPENDENT AUTHORITIES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 570

STATE OF NEW JERSEY

DATED: MAY 30, 2002

The Assembly Regulated Professions and Independent Authorities Committee reports favorably Assembly Bill No. 570.

This bill enacts the "New Jersey Pharmacy Practice Act" and repeals the current law providing for the regulation and licensure of pharmacists.

The bill reenacts most of the provisions of the current law with some changes and includes some new provisions, such as providing that pharmacists may be engaged in the management of a patient's drug, biological and device-related health care needs pursuant to a written protocol in collaboration with a licensed physician and providing for the regulation of pharmacies located outside of this State that solicit, advertise, ship, mail or deliver drugs pursuant to a valid prescription into this State. The provisions of the current law requiring utilization reviews, patient profiles and counseling and non-reproducible, non-erasable safety paper New Jersey Prescription Blanks are continued under the bill.

This bill was pre-filed for introduction in the 2002-2003 session pending technical review. As reported, the bill includes the changes required by technical review, which has been performed.

STATEMENT TO
ASSEMBLY, No. 570

with Assembly Floor Amendments
(Proposed By Assemblyman IMPREVEDUTO and Assemblywoman QUIGLEY)

ADOPTED: MARCH 13, 2003

These amendments limit the "practice of pharmacy" to those activities specified in that definition contained in the bill. The amendments further provide that the New Jersey State Board of Pharmacy, through board regulations, shall establish specific requirements, as delineated in the amendments, that are to be included in any written protocol between a physician and pharmacist. The amendments also state that any such written protocol is to be directed on a voluntary basis by a patient's physician. In addition, the amendments remove from the definition of "collaborative drug therapy management" the prescribing of drug or device therapy, stipulate that the interpretation of clinical or laboratory tests under a written protocol may be performed by a pharmacist if so agreed to by the physician in the protocol, and specify that pharmacists are to be limited to ordering or performing tests granted waived status under the "New Jersey Clinical Laboratory Improvement Act."

The amendments further state that each collaborative drug therapy management shall be between a single patient's specific physician and the patient's pharmacist or pharmacists and address that patient's specific condition, disease or diseases. Another amendment provides that a written protocol between a physician and pharmacist, with the prior consent of the patient's physician who has signed the protocol, may permit therapeutic interchange for the prescription drug originally prescribed for the patient's specific condition, disease or diseases.

An additional amendment enumerates that no pharmacist shall administer a prescription drug directly to a patient: without appropriate education or certification, as determined by the board; only for the treatment of a disease for which a nationally certified program is in effect, or as determined by the board; and only if utilized for the treatment of that disease for which the drug is prescribed or indicated or for which the collaborative drug therapy management permits. Further, the amendments provide that other than for pediatric immunizations, a pharmacist may administer drugs in immunization programs and programs sponsored by governmental agencies that are not patient specific.

Also, as stipulated in the amendments, the provisions of the bill regulating collaborative drug therapy management shall not apply to any pharmacist practicing in any hospital, provided that prescribing within these institutions takes place under the guidance of a pharmacy

and therapeutics committee in accordance with procedures as determined by regulations of the New Jersey State Board of Pharmacy.

The amendments permit a pharmacist to dispense a prescription in a different dosage form than originally prescribed if the ingredient or ingredients in the prescription are of the same chemical composition as those specified by the prescriber. The amendments also provide that the pharmacist must notify the prescriber of the change made in the dosage form in the filling of the prescription no later than 48 hours following the dispensing of the prescription.

Other provisions in the amendments cite specific criteria of what constitutes grossly unprofessional conduct, which conduct may be the basis for the New Jersey State Board of Pharmacy to refuse an application for examination or to suspend or revoke the certificate of a licensed pharmacist.

These amendments also state that the New Jersey State Board of Pharmacy shall provide counseling to any person who presents a new prescription in a manner as determined pursuant to criteria established by the board.

New language is included in the amendments enumerating tasks the pharmacy technicians may assist a registered pharmacist in performing, and those activities that are prohibited for a pharmacy technician to perform. These amendments also establish standards concerning the supervision of pharmacy technicians by a licensed pharmacist.

STATEMENT TO
[First Reprint]
ASSEMBLY, No. 570

with Assembly Floor Amendments
(Proposed By Assemblyman IMPREVEDUTO and Assemblywoman QUIGLEY)

ADOPTED: MAY 15, 2003

These amendments remove from the definition of "collaborative drug therapy management" and "practice of pharmacy" the initiating of drug or device therapy, establish a definition of "modifying" pursuant to a collaborative drug therapy management, eliminate from the definition of "therapeutic interchange" reference to a clinically equivalent drug, and specify in the definition of "pharmacy practice site" that this definition applies to any place in another state where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist rather than in any such place outside of this state.

Also, these amendments limit "collaborative drug therapy management" to those activities specified in the definition in the bill. The amendments state that the ordering of laboratory tests and the ordering or performing of clinical tests shall be based on the standing orders of a physician as set forth in the written protocol and specify that the ordering or performing of clinical tests by a pharmacist shall be only for the treatment of a disease state identified by the New Jersey State Board of Pharmacy as subject to collaborative drug therapy management.

The amendments stipulate that a pharmacist may only dispense a prescription in a different dosage form when the dosage form dispensed has the same approximate release rate as the prescription originally prescribed. In addition, the amendments provide that the New Jersey State Board of Pharmacy may determine what education and qualifications a pharmacist must satisfy before that pharmacist is permitted to administer drugs in immunization programs and programs sponsored by governmental agencies that are not patient specific.

Further, the amendments state that no collaborative drug therapy management shall include, without the prior consent of the patient's physician who has signed a protocol, therapeutic interchange at the time of dispensing. The amendments also stipulate that any person located outside the United States shall be prohibited from shipping, mailing, distributing or delivering in any manner to any person in this State legend drugs or devices approved by the federal Food and Drug Administration and available in the United States pursuant to a prescription.

STATEMENT TO
[Second Reprint]
ASSEMBLY, No. 570

with Assembly Floor Amendments
(Proposed By Assemblyman IMPREVEDUTO and Assemblywoman QUIGLEY)

ADOPTED: MAY 22, 2003

These amendments remove the provision in the bill that any person located outside the United States shall be prohibited from shipping, mailing, distributing or delivering in any manner to any person in this State legend drugs or devices approved by the federal Food and Drug Administration and available in the United States pursuant to a prescription. The amendments also stipulate that the interpretation of clinical or laboratory tests under a written protocol may only be performed by a pharmacist in direct consultation with a physician, rather than if so agreed to by the physician in the protocol.

STATEMENT TO
[Third Reprint]
ASSEMBLY, No. 570

with Senate Floor Amendments
(Proposed By Senator CARDINALE)

ADOPTED: JUNE 23, 2003

These amendments: require that pharmacies located in another state that solicit, advertise, ship, mail or deliver drugs pursuant to a valid prescription into this State must register with the New Jersey State Board of Pharmacy (board) and file certain information with the board, pay an annual registration fee not exceeding \$500, and maintain a certain level of customer service, such as a toll-free telephone service, instead of securing a permit for a pharmacy practice site; require the board and the State Board of Medical Examiners to establish specific requirements that are to be included in any written protocol between a physician and pharmacist by joint regulations; provide that each collaborative drug therapy management shall be between a single patient's specific physician and the patient's pharmacist or pharmacy; provide that a pharmacist may dispense a prescription in a different dosage form than originally prescribed if the dosage form dispensed has the appropriate release rate and the pharmacist notifies the prescriber of the change made in the dosage form in the filling of the prescription no later than 48 hours following the dispensing of the prescription; and make certain clarifying and technical amendments.

These amendments make Assembly, No. 570 (3R) identical to Senate, No. 2598 (1R).

SENATE, No. 2598

STATE OF NEW JERSEY
210th LEGISLATURE

INTRODUCED MAY 29, 2003

Sponsored by:

Senator GERALD CARDINALE

District 39 (Bergen)

Senator ROBERT W. SINGER

District 30 (Burlington, Mercer, Monmouth and Ocean)

SYNOPSIS

Enacts new law to regulate and license pharmacists.

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT regulating and licensing pharmacists and repealing various
2 parts of the statutory law.

3

4 **BE IT ENACTED** by the Senate and General Assembly of the State
5 of New Jersey:

6

7 1. a. This act shall be known and may be cited as the "New Jersey
8 Pharmacy Practice Act."

9 b. The practice of pharmacy in this State is declared a health care
10 professional practice affecting the public health, safety and welfare and
11 is subject to regulation and control in the public interest. It is further
12 declared to be a matter of public interest and concern that the practice
13 of pharmacy merits and receives the confidence of the public and that
14 only qualified persons be permitted to engage in the practice of
15 pharmacy in this State. This act shall be liberally construed to carry
16 out these objectives and purposes.

17 c. It is the purpose of this act to promote, preserve and protect the
18 public health, safety and welfare by and through the effective control
19 and regulation of the practice of pharmacy, the licensure of
20 pharmacists and the permitting, control and regulation of all pharmacy
21 practice sites, in or out of this State, that engage in the practice of
22 pharmacy.

23

24 2. As used in this act:

25 "Administer" means the direct application of a drug to the body of
26 a patient or research subject by subcutaneous, intramuscular or
27 intradermal injection, inhalation, ingestion or any other means by a
28 pharmacist engaged in collaborative practice or in accordance with
29 regulations of the board.

30 "Automated medication device" means a discrete unit that performs
31 specific drug dispensing operations.

32 "Automated medication system" means any process that performs
33 operations or activities, other than compounding or administration,
34 relative to the storage, packaging, dispensing and distribution of
35 medications and which collects, controls and maintains all transaction
36 information.

37 "Board of Pharmacy" or "board" means the New Jersey State Board
38 of Pharmacy.

39 "Certification" means a certification awarded by a recognized non-
40 government specialty organization to signify that a pharmacist has met
41 predetermined qualifications and to signify to the public that the
42 pharmacist is competent to practice in the designated specialty.

43 "Collaborative drug therapy management" means a written protocol
44 directed on a voluntary basis by a patient's physician that is between
45 a patient's physician who is treating the patient for a specific disease
46 and a pharmacist for cooperative management of a patient's drug,

1 biological and device-related health care needs, which includes:
2 collecting, analyzing and monitoring of patient data; ordering of
3 laboratory tests based on the standing orders of a physician as set forth
4 in the written protocol; ordering or performing of clinical tests based
5 on the standing orders of a physician as set forth in the written
6 protocol, which tests are granted waived status in accordance with the
7 provisions of the "New Jersey Clinical Laboratory Improvement Act,"
8 P.L.1975, c.166 (C.45:9-42.26 et seq.) and are for the treatment of a
9 disease state identified by the board as subject to collaborative drug
10 therapy management; modifying, continuing or discontinuing drug or
11 device therapy; and therapeutic drug monitoring with appropriate
12 modification to dose, dosage regimen, dosage forms or route of
13 administration. The interpretation of clinical or laboratory tests under
14 a written protocol may be performed by a pharmacist if so agreed to
15 by the physician in the protocol.

16 "Compounding" means the preparation, mixing, assembling,
17 packaging or labeling of a drug or device as the result of a
18 practitioner's prescription or initiative based on the relationship of the
19 practitioner or patient with the pharmacist in the course of
20 professional practice or for the purpose of, or incident to, research,
21 teaching or chemical analysis and not for sale or dispensing.
22 Compounding also includes the preparation of drugs or devices in
23 anticipation of prescription drug orders based on routine, regularly
24 observed prescribing patterns.

25 "Confidential information" means information that is identifiable as
26 to the patient involved that a pharmacist accesses, transmits or
27 maintains in a patient's record or which is communicated to or by the
28 patient as part of patient counseling.

29 "Credentialing" means the process by which an approved academic
30 institution awards a certificate to signify that the credentialed
31 pharmacist has completed the required courses, examinations or both,
32 that indicate advanced knowledge of a particular area of pharmacy.

33 "Deliver" or "delivery" means the actual, constructive or attempted
34 transfer of a drug or device from one person to another, whether or
35 not for consideration.

36 "Device" means an instrument, apparatus, implement, machine,
37 contrivance, implant or other similar or related article, including any
38 component part or accessory, which is required under federal law to
39 bear the label "RX Only."

40 "Dispense" or "dispensing" means the procedure entailing the
41 interpretation of a practitioner's prescription order for a drug,
42 biological or device, and pursuant to that order the proper selection,
43 measuring, compounding, labeling and packaging in a proper container
44 for subsequent administration to, or use by, a patient.

45 "Dosage form" means the physical formulation or medium in which
46 the product is intended, manufactured and made available for use,

1 including, but not limited to: tablets, capsules, oral solutions and
2 suspensions.

3 "Drug or medication" means articles recognized as drugs in any
4 official compendium, or supplement thereto, designated from time to
5 time by the board for use in the diagnosis, cure, mitigation, treatment
6 or prevention of disease in humans or other animals; articles intended
7 for use in the diagnosis, cure, mitigation, treatment or prevention of
8 disease in humans or other animals; articles intended to affect the
9 structure or any function of the body of humans or other animals,
10 except that a food, dietary ingredient or dietary supplement, as those
11 terms are defined in 21 U.S.C.s.321, is not a drug solely because the
12 label or the labeling contains such a claim; and articles intended for use
13 as a component of and articles specified in this definition of "drug or
14 medication."

15 "Drug utilization review" includes, but is not limited to, the
16 following activities:

17 (1) Evaluation of prescription drug orders and patient records for
18 known allergies, rational therapy-contraindications, appropriate dose
19 and route of administration and appropriate directions for use;

20 (2) Evaluation of prescription drug orders and patient records for
21 duplication of therapy;

22 (3) Evaluation of prescription drug orders and patient records for
23 interactions between drug-drug, drug-food, drug-disease and adverse
24 drug reactions; and

25 (4) Evaluation of prescription drug orders and patient records for
26 proper utilization, including over- or under-utilization, and optimum
27 therapeutic outcomes.

28 "Extern" means any person who is in the fifth or sixth year of
29 college or the third or fourth professional year, at an accredited school
30 or college of pharmacy approved by the board, who is assigned to a
31 training site for the purpose of acquiring accredited practical
32 experience under the supervision of the school or college at which the
33 person is enrolled.

34 "Immediate supervision" means a level of control which assures that
35 the pharmacist is physically present at the pharmacy practice site and
36 has the responsibility for the accuracy and safety with respect to the
37 actions of pharmacy technicians, interns and externs.

38 "Intern" means any person who has graduated from an accredited
39 school or college of pharmacy approved by the board, or if a foreign
40 pharmacy graduate, any person who has met all of the requirements of
41 the board, and who is being trained by an approved preceptor for the
42 purpose of acquiring accredited practical experience and who has first
43 registered for that purpose with the board.

44 "Labeling" means the process of preparing and affixing a label to
45 any drug container, exclusive however, of the labeling by a
46 manufacturer, packer or distributor of a non-prescription drug or

1 commercially packaged legend drug or device.

2 "Licensure" means the process by which the board grants
3 permission to an individual to engage in the practice of pharmacy upon
4 finding that the applicant has attained the degree of competency
5 necessary to ensure that the public health, safety and welfare will be
6 protected.

7 "Medication error" means a preventable event that may cause or
8 lead to inappropriate use of a medication or patient harm while the
9 medication is in the control of the practitioner, patient or consumer.

10 "Medication order" means a prescription for a specific patient in an
11 institutional setting.

12 "Modifying" means to change a specific drug, the dosage, or route
13 of delivery of a drug currently being administered for an existing
14 diagnosis pursuant to a collaborative drug therapy management.

15 "Non-prescription drug or device" means a drug or device which
16 may be obtained without a prescription and which is labeled for
17 consumer use in accordance with the requirements of the laws and
18 rules of this State and the federal government.

19 "Permit" means the authorization granted by the board to a site to
20 engage in the practice of pharmacy.

21 "Person" means an individual, corporation, partnership, association
22 or any other legal entity including government.

23 "Pharmaceutical care" means the provision by a pharmacist of drug
24 therapy review and other related patient care services intended to
25 achieve positive outcomes related to the treatment, cure or prevention
26 of a disease; control, elimination or reduction of a patient's symptoms;
27 or arresting or slowing of a disease process as defined by the rules and
28 regulations of the board.

29 "Pharmacist" means an individual currently licensed by this State to
30 engage in the practice of pharmacy.

31 "Pharmacist-in-charge" means a pharmacist who accepts
32 responsibility for the operation of a pharmacy practice site in
33 conformance with all laws and rules pertinent to the practice of
34 pharmacy and the distribution of drugs.

35 "Pharmacist in collaborative practice" means a pharmacist engaged
36 in the collaborative drug therapy management of a patient's drug,
37 biological and device-related health care needs pursuant to a written
38 protocol, in collaboration with a licensed physician and in accordance
39 with the board's regulations.

40 "Pharmacy practice site" means any place in this State or another
41 state where drugs are dispensed or pharmaceutical care is provided by
42 a licensed pharmacist.

43 "Pharmacy technician" means an individual working in a pharmacy
44 practice site who, under the immediate supervision of a pharmacist,
45 assists in pharmacy activities as permitted by section 41 of this act and
46 the rules and regulations of the board that do not require the

1 professional judgment of a pharmacist.

2 "Practice of pharmacy" means a health care service by a pharmacist
3 that includes: compounding, dispensing and labeling of drugs,
4 biologicals, radio pharmaceuticals or devices; overseeing automated
5 medication systems; interpreting and evaluating prescriptions;
6 administering and distributing drugs, biologicals and devices;
7 maintaining prescription drug records; advising and consulting on the
8 therapeutic values, content, hazards and uses of drugs, biologicals and
9 devices; managing and monitoring drug therapy; collecting, analyzing
10 and monitoring patient data; performing drug utilization reviews;
11 storing prescription drugs and devices; supervising technicians, interns
12 and externs; and such other acts, services, operations or transactions
13 necessary, or incidental to, providing pharmaceutical care and
14 education. In accordance with written guidelines or protocols
15 established with a licensed physician, the "practice of pharmacy" also
16 includes collaborative drug therapy management including modifying,
17 continuing or discontinuing drug or device therapy; ordering of
18 laboratory tests; and ordering and performance of clinical tests.

19 "Practitioner" means an individual currently licensed, registered or
20 otherwise authorized by the jurisdiction in which the individual
21 practices to administer or prescribe drugs in the course of professional
22 practice.

23 "Preceptor" means an individual who is a pharmacist, meets the
24 qualifications under the rules and regulations of the board, and
25 participates in the instructional training of pharmacy interns and
26 externs.

27 "Prescription" means a lawful order of a practitioner for a drug, a
28 device or diagnostic agent for a specific patient.

29 "Prescription drug" or "legend drug" means a drug which, under
30 federal law, is required to be labeled prior to being delivered to the
31 pharmacist, with either of the following statements: "Rx Only" or
32 "Caution: Federal law restricts this drug to use by, or on the order of,
33 a licensed veterinarian" or is required by any applicable federal or state
34 law, rule or regulation to be dispensed pursuant to a prescription drug
35 order or is restricted to use by a practitioner only.

36 "Registration" means the process of making a list or being enrolled
37 in an existing list.

38 "Therapeutic interchange" means the substitution and dispensing of
39 a drug chemically dissimilar from the prescription drug originally
40 prescribed.

41

42 3. The board shall enforce the provisions of this act. The board
43 shall have all of the duties, powers and authority specifically granted
44 by or necessary for the enforcement of this act, as well as such other
45 duties, powers and authority as it may be granted from time to time by
46 applicable law.

1 4. a. The board shall consist of eleven members, two of whom
2 shall be public members and one of whom shall be a state executive
3 department member appointed pursuant to the provisions of P.L.1971,
4 c.60 (C.45:1-2.1 et seq.). Each of the remaining eight members shall
5 be pharmacists. Each pharmacist member shall have at least five years
6 of experience in the practice of pharmacy in this State after licensure,
7 and shall at the time of appointment and throughout their tenure: be
8 currently licensed and in good standing to engage in the practice of
9 pharmacy in this State, and be actively engaged in the practice of
10 pharmacy in this State.

11 b. The Governor shall appoint the members of the board. Every
12 state professional pharmacy association may send to the Governor the
13 names of pharmacists having the qualifications required by this section,
14 whom the Governor may appoint to fill any vacancy occurring in the
15 board. In appointing members to the board to fill vacancies of
16 members who engage in the practice of pharmacy, the Governor shall
17 appoint members so that the membership of the board includes, at all
18 times, at least one pharmacist employed by a chain drug retailer who
19 owns or operates seven or more pharmacy practice sites, one
20 pharmacist who is employed by a health care system and one
21 pharmacist who owns a pharmacy practice site in this State.

22 c. Except for the members first appointed, members of the board
23 shall be appointed for a term of five years, except that members of the
24 board who are appointed to fill vacancies which occur prior to the
25 expiration of a former member's full term shall serve the unexpired
26 portion of that term. The terms of the members of the board shall be
27 staggered, so that the terms of no more than three members shall
28 expire in any year. Each member shall serve until a successor is
29 appointed and qualified. The present members of the board appointed
30 pursuant to R.S.45:14-1 et seq. shall serve the balance of their terms.
31 Any present board member appointed initially for a term of less than
32 five years shall be eligible to serve for two additional full terms. No
33 member of the board shall serve more than two consecutive full terms.
34 The completion of the unexpired portion of a full term shall not
35 constitute a full term for purposes of this subsection.

36 d. The Governor may remove a member of the board after a
37 hearing for misconduct, incompetency, neglect of duty or for any other
38 sufficient cause.

39
40 5. a. The board shall annually elect from among its members a
41 president and vice-president.

42 b. The position of executive director shall be held by a pharmacist
43 licensed in the State of New Jersey. The executive director shall be
44 responsible for the performance of the administrative functions of the
45 board and those other duties that the board may direct.

1 6. Each member of the board shall receive compensation pursuant
2 to section 2 of P.L.1977, c.285 (C.45:1-2.5) of \$150 per day for each
3 day on which the member is engaged in performance of the official
4 duties of the board, and shall be reimbursed for all reasonable and
5 necessary expenses incurred in connection with the discharge of those
6 official duties.

7
8 7. The board shall meet at least once every month to transact its
9 business. The board shall meet at those additional times that it may
10 determine. Additional meetings may be called by the president of the
11 board or by two-thirds of the members of the board.

12
13 8. The board shall make, adopt, amend and repeal those rules and
14 regulations necessary for the proper administration and enforcement
15 of this act. Those rules and regulations shall be promulgated in
16 accordance with the "Administrative Procedure Act," P.L.1968, c.410
17 (C.52:14B-1 et seq.).

18
19 9. a. The board shall be responsible for the control and regulation
20 of the practice of pharmacy in this State including, but not limited to,
21 the following:

22 (1) The licensing by examination or by license transfer of
23 applicants who are qualified to engage in the practice of pharmacy
24 under the provisions of this act;

25 (2) The renewal of licenses to engage in the practice of pharmacy;

26 (3) The establishment and enforcement of professional standards
27 and rules of conduct of pharmacists engaged in the practice of
28 pharmacy;

29 (4) The establishment of requirements for pharmacists to engage
30 in collaborative practice;

31 (5) The establishment of requirements for pharmacists to
32 administer drugs directly to patients;

33 (6) The enforcement of those provisions of this act relating to the
34 conduct or competence of pharmacists practicing in this State, and the
35 suspension, revocation, failure to renew or restriction of licenses to
36 engage in the practice of pharmacy pursuant to the provisions of
37 P.L.1978, c.73 (C.45:1-14 et seq.);

38 (7) The regulation of pharmacy practiced through any
39 technological means;

40 (8) The regulation and control of automated medication systems
41 and automated medication devices within or outside of pharmacy
42 practice sites;

43 (9) The right to seize any drugs and devices found by the board to
44 constitute an imminent danger to the public health and welfare;

45 (10) The establishment of minimum specifications for record
46 keeping, prescription and patient profile record maintenance, pharmacy

1 practice sites including, but not limited to, the physical premises,
2 technical equipment, environment, supplies, personnel and procedures
3 for the storage, compounding and dispensing of drugs or devices, and
4 for the monitoring of drug therapy;

5 (11) The inspection of any pharmacy practice site at all reasonable
6 hours for the purpose of determining if any provisions of the laws
7 governing the legal distribution of drugs or devices or the practice of
8 pharmacy are being violated. The board, its officers, inspectors and
9 representatives shall cooperate with all agencies charged with the
10 enforcement of the laws of the United States, of this State, and of all
11 other states relating to drugs, devices and the practice of pharmacy;

12 (12) The inspection of prescription files and the prescription
13 records of a pharmacy and the removal from the files and taking
14 possession of any original prescription, providing that the authorized
15 agent removing or taking possession of an original prescription shall
16 place in the file from which it was removed a copy certified by that
17 person to be a true copy of the original prescription removed;
18 provided further, that the original copy shall be returned by the board
19 to the file from which it was removed after it has served the purpose
20 for which it was removed;

21 (13) The establishment of requirements for patient counseling,
22 patient profiles and drug utilization reviews;

23 (14) The establishment of regulations to protect the health and
24 safety of pharmacy patients; and

25 (15) The prescribing or changing of the charges for examinations,
26 certifications, licensures, renewals and other services performed
27 pursuant to P.L.1974, c.46 (C.45:1-3.1 et seq.).

28 b. The board shall have those other duties, powers and authority
29 as may be necessary to the enforcement of this act and to the
30 enforcement of rules and regulations of the board, which may include,
31 but not be limited to, the following:

32 (1) The determination and issuance of standards, recognition and
33 approval of degree programs of schools and colleges of pharmacy
34 whose graduates shall be eligible for licensure in this State, and the
35 specifications and enforcement of requirements for practical training,
36 including internships;

37 (2) The registration of externs, interns, pharmacy preceptors and
38 pharmacy technicians;

39 (3) The regulation of the training, qualifications and conduct of
40 applicants, externs, interns, pharmacy preceptors and pharmacy
41 technicians;

42 (4) The collection of professional demographic data;

43 (5) The joining with those professional organizations and
44 associations organized to promote the improvement of the standards
45 of the practice of pharmacy for the protection of the health and
46 welfare of the public or whose activities assist and facilitate the work

1 of the board;

2 (6) The establishment of a bill of rights for patients concerning the
3 health care services a patient may expect in regard to pharmaceutical
4 care;

5 (7) The engagement in activities to educate consumers, to assist
6 them in obtaining information necessary to make decisions about
7 medication issues;

8 (8) The establishment of standards for the continuing education of
9 registered pharmacists;

10 (9) The establishment of rules and regulations for extraordinary
11 emergency situations that interfere with the ability to practice under
12 the current rules and regulations;

13 (10) The establishment of guidelines for board approved pilot
14 programs. The guidelines shall be complied with to implement a
15 program that may not be presently acknowledged in this act or its rules
16 or regulations; and

17 (11) The assurance that any credentialing or certification of a
18 pharmacist is not misleading to the public.

19 c. (1) The board may place under seal all drugs, biologicals, radio
20 pharmaceuticals or devices that are owned by or in the possession,
21 custody or control of a licensee or permit holder at the time his license
22 or permit is suspended or revoked or at the time the board refused to
23 renew his license. Except as otherwise provided in this section, drugs,
24 biologicals, radio pharmaceuticals or devices that are sealed pursuant
25 to this paragraph shall not be disposed of until appeal rights under the
26 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.)
27 have expired, or an appeal filed pursuant to that act has been
28 determined. The court, involved in an appeal filed pursuant to the
29 "Administrative Procedure Act," may order the board, during the
30 pendency of the appeal, to sell sealed drugs, biologicals and radio
31 pharmaceuticals that are perishable. The proceeds of a sale shall be
32 deposited with the court.

33 (2) Notwithstanding any provisions of this act to the contrary,
34 whenever a duly authorized representative of the board finds, or has
35 probable cause to believe, that any drug or device is outdated,
36 adulterated or misbranded within the meaning of the "Federal Food,
37 Drug, and Cosmetic Act," 21 U.S.C.s.301 et seq., the representative
38 shall affix to that drug or device a tag or other appropriate marking
39 giving notice that the article is or is suspected of being outdated,
40 adulterated or misbranded, had been detained or embargoed, and
41 warning all persons not to remove or dispose of the article by sale or
42 otherwise until provision for removing or disposal is given by the
43 board, its agent or the court. No person shall remove or dispose of an
44 embargoed drug or device by sale or otherwise without the permission
45 of the board or its agent or, after summary proceedings have been
46 instituted, without permission of the court.

1 (3) When a drug or device detained or embargoed under paragraph
2 (2) of this subsection c. has been declared by the representative to be
3 outdated, adulterated or misbranded, the board shall, as soon as
4 practical thereafter, petition the judge of the court in which
5 jurisdiction the article is detained or embargoed for an order for
6 condemnation of that article. If the judge determines that this drug or
7 device so detained or embargoed is not adulterated, outdated or
8 misbranded, the board shall direct the immediate removal of the tag or
9 other marking.

10 (4) If the court finds that a detained or embargoed drug or device
11 is adulterated, outdated or misbranded, that drug or device, after entry
12 of the decree, shall be destroyed at the expense of the owner under the
13 supervision of a board representative and all court costs and fees,
14 storage and other proper expenses shall be borne by the owner of that
15 drug or device. When the outdated, adulteration or misbranding can
16 be corrected by proper labeling or processing of the drug or device,
17 the court, after entry of the decree and after the costs, fees and
18 expenses have been paid and a good and sufficient bond has been
19 posted, may direct that the drug or device be delivered to the owner
20 thereof for labeling or processing under the supervision of a board
21 representative. Expense of that supervision shall be paid by the owner.
22 The bond shall be returned to the owner of the drug or device on
23 representation to the court by the board that the drug or device is no
24 longer in violation of the embargo and the expense of supervision has
25 been paid.

26 d. Except as otherwise provided to the contrary, the board shall
27 exercise all of its duties, powers and authority in accordance with the
28 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
29 seq.).

30

31 10. a. Except as otherwise provided in this act, it shall be unlawful
32 for any individual to engage in the practice of pharmacy unless
33 currently licensed to practice under the provisions of this act.

34 b. The provisions of this act shall not apply to the sale of any drug
35 by a manufacturer or wholesaler or pharmacy to each other or to a
36 physician, dentist, veterinarian or other person licensed to prescribe
37 such drugs in their professional practice.

38 c. Practitioners authorized under the laws of this State to
39 compound drugs and to dispense drugs directly to their patients in the
40 practice of their respective professions shall meet the same storage,
41 handling, security, counseling, labeling, packaging and record keeping
42 requirements for the dispensing of drugs applicable to pharmacists.

43

44 11. To obtain a license to engage in the practice of pharmacy, the
45 applicant shall:

46 a. Have submitted a written application in the form prescribed by

- 1 the board;
- 2 b. Have attained the age of 18 years;
- 3 c. Be of good moral character;
- 4 d. Have graduated and received a professional degree from a
- 5 college or school of pharmacy that has been approved by the board;
- 6 e. Have completed an internship or other program that has been
- 7 approved by the board, or demonstrated to the board's satisfaction
- 8 experience in the practice of pharmacy which meets or exceeds the
- 9 minimum internship requirements of the board;
- 10 f. Have successfully passed an examination or examinations as
- 11 determined by the board; and
- 12 g. Have paid the fees specified by the board for the examination
- 13 and any related materials, and have paid for the issuance of the license.
- 14

15 12. The examination for licensure shall measure the competence of

16 the applicant to engage in the practice of pharmacy. The board may

17 employ, cooperate and contract with any organization or consultant in

18 the preparation and grading of an examination, but shall retain the sole

19 discretion and responsibility for determining which applicants have

20 successfully passed the examination.

21

22 13. a. All applicants for licensure by examination shall obtain

23 practical experience in the practice of pharmacy under terms and

24 conditions determined by the board.

25 b. The board may establish licensure requirements for interns and

26 standards for internship, or any other experiential program necessary

27 to qualify an applicant for the licensure examination, and shall also

28 determine the qualifications of preceptors used in practical experience

29 programs.

30

31 14. a. In order for a pharmacist currently licensed in another

32 jurisdiction to obtain a license as a pharmacist by license transfer in

33 this State, an applicant shall:

34 (1) Have submitted a written application in the form prescribed by

35 the board;

36 (2) Have attained the age of 18 years;

37 (3) Have good moral character;

38 (4) Have engaged in the practice of pharmacy for a period of at

39 least 1,000 hours within the last two years or have met, immediately

40 prior to application, the internship requirements of this State within

41 the one-year period immediately preceding the date of application;

42 (5) Have presented to the board proof of initial licensure by

43 examination and proof that the license is in good standing;

44 (6) Have presented to the board proof that any other license

45 granted to the applicant by any other state has not been suspended,

46 revoked or otherwise restricted for any reason except nonrenewal or

1 for the failure to obtain the required continuing education credits in
2 any state where the applicant is currently licensed but not engaged in
3 the practice of pharmacy;

4 (7) Have paid the fees specified by the board;

5 (8) Have graduated and received a professional degree from a
6 college or school of pharmacy approved by the board; and

7 (9) Have met any other requirements as established by the board
8 by regulation.

9 b. No applicant shall be eligible for license transfer unless the
10 applicant holds a current valid license in a state that grants licensure
11 transfer to pharmacists duly licensed by examination in this State.

12 c. In order for a pharmacist applicant with a pharmacy degree from
13 a foreign country or a college of pharmacy not approved by the board
14 to obtain a license as a pharmacist, that applicant shall meet those
15 requirements as established by the board by regulation.

16

17 15. a. The board shall require each person registered as a
18 pharmacist, as a condition for biennial renewal certification, to
19 complete continuing pharmacy education during each biennial period
20 immediately preceding the date of renewal and submit proof thereof to
21 the board.

22 b. The board shall:

23 (1) Establish standards for continuing pharmacy education,
24 including the number of credits, the subject matter and content of
25 courses of study, the selection of instructors and the type of
26 continuing education credits required of a registered pharmacist as a
27 condition of biennial registration;

28 (2) Approve educational programs offering credit towards
29 continuing pharmacy education requirements; and

30 (3) Approve other equivalent educational programs, including, but
31 not limited to, home study courses, and establish procedures for the
32 issuance of credit upon satisfactory proof of the completion of these
33 programs. In the case of continuing education courses and programs,
34 each hour of instruction shall be equivalent to one credit.

35 c. (1) The board shall only approve programs that are provided on
36 a nondiscriminatory basis. The board shall permit any pharmacy
37 association or organization offering a continuing pharmacy education
38 program approved by the board pursuant to subsection b. of this
39 section to impose a reasonable differential in registration fees for
40 courses upon registered pharmacists who are not members of that
41 pharmacy association or organization. The board may approve
42 programs held within or outside the State.

43 (2) In no event shall the board grant credits for, or approve as, a
44 component of a continuing education program:

45 (a) participation in a routine business portion of a meeting of a
46 pharmacy association or organization; or

1 (b) any presentation that is offered to sell a product or promote a
2 business enterprise.

3 d. (1) The board may, in its discretion, waive requirements for
4 continuing education on an individual basis for reasons of hardship,
5 such as illness or disability, retirement of the registration certificate,
6 or any other good cause.

7 (2) The board shall not require completion of continuing education
8 credits for an initial renewal of registration.

9 (3) If a pharmacist completes a number of continuing education
10 credit hours in excess of the number required for a biennial period, the
11 board may allow, by rule or regulation, credits to be carried over to
12 satisfy the pharmacist's continuing education requirement for the next
13 biennial renewal period, but shall not be applicable thereafter.

14

15 16. a. A practitioner practicing in this State shall use non-
16 reproducible, non-erasable safety paper New Jersey Prescription
17 Blanks bearing that practitioner's license number whenever the
18 practitioner issues prescriptions for controlled dangerous substances,
19 prescription legend drugs or other prescription items. The prescription
20 blanks shall be secured from a vendor approved by the Division of
21 Consumer Affairs in the Department of Law and Public Safety.

22 b. A licensed practitioner practicing in this State shall maintain a
23 record of the receipt of New Jersey Prescription Blanks. The
24 practitioner shall notify the Office of Drug Control in the Division of
25 Consumer Affairs as soon as possible but no later than 72 hours of
26 being made aware that any New Jersey Prescription Blank in the
27 practitioner's possession has been stolen. Upon receipt of notification,
28 the Office of Drug Control shall take appropriate action, including
29 notification to the Department of Human Services and the Attorney
30 General.

31

32 17. a. Prescriptions issued by a health care facility licensed
33 pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) shall be written on
34 non-reproducible, non-erasable safety paper New Jersey Prescription
35 Blanks. The prescription blanks shall be secured from a vendor
36 approved by the Division of Consumer Affairs in the Department of
37 Law and Public Safety. The New Jersey Prescription Blanks shall bear
38 the unique provider number assigned to that health care facility for the
39 issuing of prescriptions for controlled dangerous substances,
40 prescription legend drugs or other prescription items.

41 b. A health care facility shall maintain a record of the receipt of
42 New Jersey Prescription Blanks. The health care facility shall notify
43 the Office of Drug Control in the Division of Consumer Affairs as
44 soon as possible but no later than 72 hours of being made aware that
45 any New Jersey Prescription Blank in the facility's possession has been
46 stolen. Upon receipt of notification, the Office of Drug Control shall

1 take appropriate action including notification to the Department of
2 Human Services and the Attorney General.

3
4 18. A prescription issued by a practitioner or health care facility
5 shall not be filled by a pharmacist unless the prescription is issued on
6 a New Jersey Prescription Blank bearing the practitioner's license
7 number or the unique provider number assigned to a health care
8 facility.

9
10 19. a. Nothing contained in this act shall preclude a practitioner
11 from transmitting to a pharmacist by telephone or electronic means a
12 prescription, as otherwise authorized by law, if that practitioner
13 provides the practitioner's Drug Enforcement Administration
14 registration number or practitioner's license number, or any other
15 federally identified number, as appropriate, to the pharmacist at the
16 time the practitioner transmits the prescription.

17 b. Except as may be otherwise permitted by law, no prescription
18 for any Schedule II controlled dangerous substance shall be given or
19 transmitted to pharmacists, in any other manner, than in writing signed
20 by the practitioner giving or transmitting the same, nor shall such
21 prescription be renewed or refilled. The requirement in this subsection
22 that a prescription for any controlled dangerous substance be given or
23 transmitted to pharmacists in writing signed by the practitioner shall
24 not apply to a prescription for a Schedule II drug if that prescription
25 is transmitted or prepared in compliance with federal and State
26 regulations.

27
28 20. The Division of Consumer Affairs in the Department of Law
29 and Public Safety shall establish the format for uniform, non-
30 reproducible, non-erasable safety paper prescription blanks, to be
31 known as New Jersey Prescription Blanks, which format shall include
32 an identifiable logo or symbol that will appear on all prescription
33 blanks. The division shall approve a sufficient number of vendors to
34 ensure production of an adequate supply of New Jersey Prescription
35 Blanks for practitioners and health care facilities statewide.

36
37 21. A pharmacist may dispense a prescription in a different dosage
38 form than originally prescribed if the pharmacist notifies the prescriber
39 no later than 48 hours following the dispensing of the prescription,
40 provided the dosage form dispensed has the same approximate drug
41 release rate.

42
43 22. In establishing requirements for pharmacists to engage in
44 collaborative practice as provided in paragraph (4) of subsection a. of
45 section 9 of this act, the board shall include in these requirements, but
46 not be limited to, provisions that any written protocol between a

- 1 physician and pharmacist:
- 2 a. is agreed to by both the physician and the pharmacist;
- 3 b. identifies, by name and title, each physician and each pharmacist
4 who is permitted to participate in a patient's collaborative drug therapy
5 management;
- 6 c. specifies the functions and responsibilities the pharmacist will be
7 performing;
- 8 d. is available at the practice sites of the pharmacist and physician
9 and made available at each site to the patient;
- 10 e. is initiated and utilized at the sole discretion of the physician for
11 a specific patient;
- 12 f. may be terminated at any time by either party by written
13 documentation;
- 14 g. establishes when physician notification is required, the physician
15 chart update interval, and an appropriate time frame within which the
16 pharmacist must notify the physician of any change in dose, duration
17 or frequency of medication prescribed; and
- 18 h. remains in effect for a period not to exceed two years upon the
19 conclusion of which, or sooner, the parties shall review the protocol
20 and make a determination as to its renewal, modification or
21 termination.
- 22
- 23 23. a. Each collaborative drug therapy management shall be
24 between a single patient's specific physician and the patient's
25 pharmacist or pharmacy and address that patient's specific condition,
26 disease or diseases.
- 27 b. No collaborative drug therapy management shall include,
28 without the prior consent of the patient's physician who has signed the
29 protocol, therapeutic interchange at the time of dispensing, provided
30 that written confirmation of this prior consent, which may be by
31 electronic means, shall be obtained pursuant to record keeping
32 guidelines to be established by the board.
- 33
- 34 24. a. No pharmacist shall administer a prescription medication
35 directly to a patient without appropriate education or certification, as
36 determined by the board. Such medication shall only be for the
37 treatment of a disease for which a nationally certified program is in
38 effect, or as determined by the board, and only if utilized for the
39 treatment of that disease for which the medication is prescribed or
40 indicated or for which the collaborative drug therapy management
41 permits.
- 42 b. Notwithstanding any law, rule or regulation to the contrary,
43 other than for pediatric immunizations, a pharmacist may administer
44 drugs in immunization programs and programs sponsored by
45 governmental agencies that are not patient specific provided the
46 pharmacist is appropriately educated and qualified, as determined by

1 the board.

2

3 25. The provisions of this act regulating collaborative drug therapy
4 management shall not apply to any pharmacist practicing in a hospital,
5 provided that prescribing within these institutions takes place under
6 the guidance of a pharmacy and therapeutics committee in accordance
7 with procedures as determined by regulations of the board.

8

9 26. In addition to the provisions of section 8 of P.L.1978, c.73
10 (C.45:1-21), the board may refuse an application for examination or
11 may suspend or revoke the certificate of a licensed pharmacist upon
12 proof satisfactory to the board that such licensed pharmacist is guilty
13 of grossly unprofessional conduct and the following acts are hereby
14 declared to constitute grossly unprofessional conduct for the purpose
15 of this act:

16 a. Paying rebates or entering into an agreement for payment of
17 rebates to any physician, dentist or other person for the recommending
18 of the services of any person.

19 b. The providing or causing to be provided to a physician, dentist,
20 veterinarian or other person authorized to prescribe, prescription
21 blanks or forms bearing the pharmacist's or pharmacy's name, address
22 or other means of identification.

23 c. The claiming of professional superiority in the compounding or
24 filling of prescriptions or in any manner implying professional
25 superiority which may reduce public confidence in the ability,
26 character or integrity of other pharmacists.

27 d. Fostering the interest of one group of patients at the expense of
28 another which compromises the quality or extent of professional
29 services or facilities made available.

30 e. The distribution of premiums or rebates of any kind whatever in
31 connection with the sale of drugs and medications provided, however,
32 that trading stamps and similar devices shall not be considered to be
33 rebates for the purposes of this act and provided further that
34 discounts, premiums and rebates may be provided in connection with
35 the sale of drugs and medications to any person who is 60 years of age
36 or older.

37 f. Advertising of prescription drug prices in a manner inconsistent
38 with rules and regulations promulgated by the Director of the Division
39 of Consumer Affairs, except that no advertising of any drug or
40 substance shall be authorized unless the Commissioner of Health and
41 Senior Services shall have determined that the advertising is not
42 harmful to public health, safety and welfare.

43 Before a certificate shall be refused, suspended or revoked, the
44 accused person shall be furnished with a copy of the complaint and
45 given a hearing before the board. Any person whose certificate is so
46 suspended or revoked shall be deemed an unlicensed person during the

1 period of such suspension or revocation, and as those shall be subject
2 to the penalties prescribed in this act, but that person may, at the
3 discretion of the board, have his certificate reinstated at any time
4 without an examination, upon application to the board. Any person to
5 whom a certificate shall be denied by the board or whose certificate
6 shall be suspended or revoked by the board shall have the right to
7 review that action by appeal to the Appellate Division of the Superior
8 Court in lieu of prerogative writ.

9
10 27. a. A pharmacist shall conduct a prospective drug utilization
11 review before each new medication is dispensed or delivered to a
12 patient.

13 b. A pharmacist shall conduct a prospective drug utilization review
14 in accordance with the provisions of this section before refilling a
15 prescription or medication order to the extent he deems appropriate in
16 his professional judgment.

17 c. A pharmacist shall exercise independent professional judgment
18 in deciding whether or not to dispense or refill a prescription or
19 medication order. In determining to dispense or refill a prescription
20 or medication order, the decision of the pharmacist shall not be
21 arbitrary but shall be based on professional experience, knowledge or
22 available reference materials.

23
24 28. A pharmacist or his designee shall offer to provide counseling
25 to any person who presents a new prescription in a manner as
26 determined pursuant to criteria established by the board.

27
28 29. a. A patient profile system shall be maintained by all
29 pharmacies for persons for whom medications are dispensed. The
30 patient profile record system shall enable the dispensing pharmacist to
31 identify previously dispensed medication at the time a prescription is
32 presented for dispensing.

33 b. The following information generated or transferred to the
34 individual pharmacy practice site shall be recorded in the patient
35 profile system:

36 (1) The family and the first name of the person for whom the
37 medication is intended (the patient);

38 (2) The street address and telephone number of the patient;

39 (3) Indication of the patient's age, birth date or age group (infant,
40 child, adult) and gender;

41 (4) The height, weight and other patient specific criteria for those
42 medications that are height or weight dose dependent;

43 (5) The original or refill date the medication is dispensed and the
44 initials of the dispensing pharmacist, if those initials and date are not
45 recorded on the original prescription or in any other record approved
46 by the board;

- 1 (6) The number or designation identifying the prescription;
- 2 (7) The practitioner's name;
- 3 (8) The name, strength and quantity of the drug dispensed;
- 4 (9) The individual history, if significant, including known allergies
- 5 and drug reactions, known diagnosed disease states and a
- 6 comprehensive list of medications and relevant devices; and
- 7 (10) Any additional comments relevant to the patient's drug use,
- 8 which may include any failure to accept the pharmacist's offer to
- 9 counsel.

10 c. The information obtained shall be recorded in the patient's
11 manual or electronic profile, or in the prescription signature log, or in
12 any other system of records, and may be considered by the pharmacist
13 in the exercise of his professional judgment concerning both the offer
14 to counsel and content of counseling. The absence of any record of a
15 failure to accept the pharmacist's offer to counsel shall be presumed to
16 signify that the offer was accepted and that the counseling was
17 provided.

18

19 30. a. All pharmacy practice sites, in this State or another state,
20 which engage in the practice of pharmacy in the State of New Jersey,
21 shall be issued a permit by the board, and shall annually renew their
22 permit with the board. If operations are conducted at more than one
23 location, each location shall be issued a permit by the board for the
24 dispensing of medicine.

25 b. The board may determine by rule or regulation the permit
26 classifications of all pharmacy practice sites issued a permit under this
27 act, and establish minimum standards for pharmacy practice sites.

28 c. The board shall establish by rule or regulation the criteria which
29 each site shall meet to qualify for a permit in each classification. The
30 board may issue permits with varying restrictions to pharmacy practice
31 sites if the board deems it necessary.

32 d. Each holder of a pharmacy practice site permit shall ensure that
33 a licensed pharmacist be immediately available on the premises to
34 provide pharmacy services at all times the pharmacy practice site is
35 open.

36 e. Each pharmacy practice site shall have a pharmacist-in-charge.
37 The pharmacist-in-charge and the owner of a pharmacy practice site
38 shall be responsible for any violation of any laws or regulations
39 pertaining to the practice of pharmacy.

40 f. The board may enter into agreements with other states or with
41 third parties for the purpose of exchanging information concerning the
42 granting of permits and the inspection of pharmacy practice sites
43 located in this State and those located outside this State.

44 g. The board may deny, suspend, revoke, restrict or refuse to
45 renew a permit for a pharmacy practice site that does not comply with
46 the provisions of this act.

1 31. a. The board shall specify by rule or regulation the permit
2 application procedures to be followed, including, but not limited to,
3 the specification of forms to be used, the time and place the
4 application is to be made and the fees to be charged.

5 b. Applicants for a permit to operate a pharmacy practice site
6 within this State shall file with the board a verified application
7 containing the information that the board requires of the applicant
8 relative to the qualifications for the specific permit.

9 c. The board shall specify, by rule or regulation, minimum
10 standards for any pharmacy practice site that has employees or
11 personnel engaged in the practice of pharmacy that routinely serves
12 New Jersey residents. Pharmacy practice sites located in New Jersey
13 shall be operated at all times under the immediate supervision of a
14 pharmacist licensed to practice in this State.

15 d. Permits issued by the board pursuant to this act shall not be
16 transferable or assignable without the approval of the board.

17
18 32. No person shall carry on, conduct or transact business under
19 a name which contains as a part thereof the words "pharmacist,"
20 "pharmacy," "apothecary," "apothecary shop," "druggist," "drug" or
21 any word or words of similar or like import, or in any manner by
22 advertisement, circular, poster, sign or otherwise describe or refer to
23 the place of business by the terms "pharmacy," "apothecary,"
24 "apothecary shop," "chemist's shop," "drug store," "drugs" or any
25 word or words of similar or like import unless the place of business is
26 a currently licensed pharmacy practice site operated or managed at all
27 times by a pharmacist.

28
29 33. This act shall not prohibit, restrict or otherwise interfere with
30 the sale of non-prescription drugs and devices at places other than a
31 pharmacy practice site or by persons in this State who are not licensed
32 pharmacists.

33
34 34. a. Any pharmacy practice site located in another state which
35 ships, mails, distributes or delivers in any manner, legend drugs or
36 devices pursuant to a prescription into this State, shall have a permit
37 for a pharmacy practice site issued by the board.

38 b. Any person located outside the United States shall be prohibited
39 from shipping, mailing, distributing or delivering in any manner to any
40 person in this State legend drugs or devices approved by the federal
41 Food and Drug Administration and available in the United States
42 pursuant to a prescription.

43
44 35. a. All licensed pharmacy practice sites shall report to the board
45 the occurrences of any of the following:

- 46 (1) Closing of the pharmacy practice site;

- 1 (2) Change of ownership, location, interior site design permit
- 2 classification or pharmacist-in-charge of the pharmacy practice site;
- 3 (3) Any significant theft or loss of legend drugs or devices;
- 4 (4) Disasters, accidents, any theft, destruction or loss of records
- 5 required to be maintained by State or federal law;
- 6 (5) Any pharmacy malpractice liability insurance claim settlement,
- 7 judgment or arbitration award in excess of \$10,000 to which an owner,
- 8 an employee of, or the pharmacy practice site itself is a party; and
- 9 (6) Any and all other matters and occurrences as the board may
- 10 require by rule or regulation.
- 11 b. The manner, time and content of the notification shall be
- 12 prescribed by rule or regulation by the board.
- 13
- 14 36. a. No pharmacy practice site shall operate until it has been
- 15 issued a permit by the board.
- 16 b. The board may suspend, revoke, deny, restrict or refuse to
- 17 renew the permit of any pharmacy practice site on any of the following
- 18 grounds:
- 19 (1) Findings by the board that any conduct of the permit holder or
- 20 applicant is violative of any federal, State or local laws or regulations
- 21 relating to the practice of pharmacy;
- 22 (2) A conviction of the permit holder or applicant under federal,
- 23 State or local laws for a crime of moral turpitude or a crime that
- 24 relates adversely to the practice of pharmacy;
- 25 (3) Materially false or fraudulent information contained within any
- 26 application made to the board or in any application relating to drug or
- 27 device prescribing, dispensing or administration;
- 28 (4) Suspension or revocation by federal, State or local government
- 29 of any license or permit relating to the practice of pharmacy currently
- 30 or previously held by the applicant or permit holder;
- 31 (5) Utilizing a permit to obtain remuneration by fraud,
- 32 misrepresentation or deception;
- 33 (6) Dealing with drugs or devices that are known or should have
- 34 been known as stolen drugs or devices;
- 35 (7) Purchasing or receiving of a drug or device by a permit holder
- 36 or for use at a pharmacy practice site from a source that is not licensed
- 37 under the laws of the State, except where otherwise provided;
- 38 (8) Intensive and ongoing failure to provide additional personnel,
- 39 automation and technology as is necessary to ensure that the licensed
- 40 pharmacist on duty has sufficient time to utilize the professional's
- 41 knowledge and training and to competently perform the functions of
- 42 a licensed pharmacist as required by law;
- 43 (9) Violation of any of the provisions of the "New Jersey
- 44 Controlled Dangerous Substances Act," P.L.1970, c.226 (C.24:21-1
- 45 et seq.) by the applicant, permit holder or occurring at the pharmacy
- 46 practice site; or

1 (10) Violations of any of the provisions of P.L.1978, c.73 (C.45:1-
2 14 et seq.) by the applicant, permit holder or occurring at the
3 pharmacy practice site.

4 c. Reinstatement of a permit that has been suspended or restricted
5 by the board may be granted in accordance with the procedures
6 specified by section 6 of P.L.1999, c.403 (C.45:1-7.2).

7
8 37. Confidential information is declared to be privileged and shall
9 not be released except to the patient or, as the patient consents, to
10 those practitioners, other authorized health care professionals and
11 other pharmacists if in the pharmacist's professional judgement, the
12 release is necessary to protect the patient's health and well being; to
13 persons or governmental agencies authorized by law to receive such
14 confidential information, regardless of whether that information is
15 received on the telephone or is in the form of paper, preserved on
16 microfilm, or is stored by electronic means; or to the payor or payor's
17 agent.

18
19 38. A person who in good faith and without malice provides to the
20 board any information concerning any act by a pharmacist licensed by
21 the board which the person has reasonable cause to believe involves
22 misconduct that may be subject to disciplinary action by the board, or
23 any information relating to such conduct requested by the board in the
24 exercise of its statutory responsibilities or which may be required by
25 statute, shall not be liable for civil damages in any cause of action
26 arising out of the provision of such information or services.

27
28 39. a. Any person who is licensed in this State as a pharmacist on
29 the effective date of this act may continue to practice under his current
30 license until its expiration, and to obtain a license under this act
31 without examination upon payment of a fee.

32 b. Any site with a permit in this State as a pharmacy practice site
33 on the effective date of this act may continue to operate under its
34 current permit until its expiration.

35
36 40. This act shall not affect the orders, rules and regulations
37 regarding the practice of pharmacy made or promulgated by the board
38 created pursuant to R.S.45:14-1 et seq. prior to the effective date of
39 this act.

40
41 41. a. Pharmacy technicians may assist a licensed pharmacist in
42 performing the following tasks:

43 (1) Retrieval of prescription files, patient files and profiles and
44 other records, as determined by the board, pertaining to the practice
45 of pharmacy;

46 (2) Data entry;

- 1 (3) Label preparation; and
- 2 (4) Counting, weighing, measuring, pouring and compounding of
- 3 prescription medication or stock legend drugs and controlled
- 4 substances.
- 5 b. Pharmacy technicians may accept authorization from a patient
- 6 for a prescription refill, or from a physician or the physician's agent for
- 7 a prescription renewal, provided that the prescription remains
- 8 unchanged. As used in this section, "prescription refill" means the
- 9 dispensing of medications pursuant to a prescriber's authorization
- 10 provided on the original prescription and "prescription renewal" means
- 11 the dispensing of medications pursuant to a practitioner's authorization
- 12 to fill an existing prescription that has no refills remaining.
- 13 c. Pharmacy technicians shall not:
- 14 (1) Receive new verbal prescriptions;
- 15 (2) Interpret a prescription or medication order for therapeutic
- 16 acceptability and appropriateness;
- 17 (3) Verify dosage and directions;
- 18 (4) Engage in prospective drug review;
- 19 (5) Provide patient counseling;
- 20 (6) Monitor prescription usage;
- 21 (7) Override computer alerts without first notifying the pharmacist;
- 22 (8) Transfer prescriptions from one pharmacy to another pharmacy;
- 23 or
- 24 (9) Violate patient confidentiality.
- 25 d. Except as provided in subsection e. of this section, a pharmacist
- 26 shall not supervise more than two pharmacy technicians.
- 27 e. A pharmacy that wishes to employ a licensed pharmacist to
- 28 pharmacy technician ratio greater than established in accordance with
- 29 subsection d. of this section, shall:
- 30 (1) Establish written job descriptions, task protocols and policies
- 31 and procedures that pertain to the duties performed by the pharmacy
- 32 technician;
- 33 (2) Ensure and document that each pharmacy technician pass the
- 34 National Pharmacy Technician Certification Examination and fulfill the
- 35 requirements to maintain this status, or complete a program which
- 36 includes a testing component and which has been approved by the
- 37 board as satisfying the criteria as set forth in subsection f. of this
- 38 section;
- 39 (3) Ensure that each pharmacy technician is knowledgeable in the
- 40 established job descriptions, task protocols and policies and
- 41 procedures in the pharmacy setting in which the technician is to
- 42 perform his duties;
- 43 (4) Ensure that the duties assigned to any pharmacy technician do
- 44 not exceed the established job descriptions, task protocols and policies
- 45 and procedures;
- 46 (5) Ensure that each pharmacy technician receives in-service

- 1 training before the pharmacy technician assumes his responsibilities
2 and maintain documentation thereof;
- 3 (6) Require and maintain on site a signed patient confidentiality
4 statement from each technician;
- 5 (7) Provide immediate personal supervision; and
- 6 (8) Provide the board, upon request, with a copy of the established
7 job descriptions, task protocols and policies and procedures for all
8 pharmacy technician duties.
- 9 f. If the pharmacist to pharmacy technician ratio is greater than the
10 ratio established in accordance with the provisions of subsection d. of
11 this section, the pharmacy shall maintain a policy and procedure
12 manual with regard to pharmacy technicians, which shall include the
13 following:
- 14 (1) Supervision by a pharmacist;
- 15 (2) Confidentiality safeguards of patient information;
- 16 (3) Minimum qualifications;
- 17 (4) Documentation of in-service education or ongoing training and
18 demonstration of competency, specific to practice site and job
19 function;
- 20 (5) General duties and responsibilities of pharmacy technicians;
- 21 (6) Retrieval of prescription files, patient files, patient profile
22 information and other records pertaining to the practice of pharmacy;
- 23 (7) All functions related to prescription processing;
- 24 (8) All functions related to prescription legend drug and controlled
25 dangerous substance ordering and inventory control;
- 26 (9) Prescription refill and renewal authorization;
- 27 (10) Procedures dealing with documentation and records required
28 for controlled dangerous substance and prescription legend drugs;
- 29 (11) Procedures dealing with medication errors, including
30 classification of medication errors;
- 31 (12) Pharmacy technician functions related to automated systems;
- 32 (13) Functions that may not be performed by pharmacy technicians;
- 33 and
- 34 (14) A form signed by the pharmacy technician which verifies that
35 the manual has been reviewed by the technician.
- 36 g. The pharmacist in charge shall review the policy and procedure
37 manual at least every two years and, if necessary, amend the manual
38 as needed. Documentation of the review shall be made available to the
39 board upon request.
- 40 h. Pharmacy technicians shall wear an identification tag, which
41 shall include at least their first name, the first initial of their last name
42 and title.
- 43 i. On pharmacy permit renewal applications, the pharmacy shall list
44 the name and address of all pharmacy technicians which it currently
45 employs.
- 46 j. When pharmacy technicians are engaged in any activities

1 permitted in accordance with the provisions of this section, the
2 licensed pharmacists on site shall be responsible for these activities.

3
4 42. R.S.45:14-1 et seq.; section 6 of P.L.1970, c.331 (C.45:14-
5 3.1); section 4 of P.L.1991, c.304 (C.45:14-3.2) P.L.1946, c.177
6 (C.45:14-7.2); P.L.1948, c.50 (C.45:14-7.3); P.L.1969, c.164
7 (C.45:14-8.1); P.L.1944, c.132 (C.45:14-11.1); P.L.1995, c.79
8 (C.45:14-11.11 through 45:14-11.16), section 3 of P.L.1965, c.120
9 (C.45:14-12.1); P.L.1996, c.154 (C.45:14-14.1 through 45:14-14.6);
10 P.L.1993, c.120 (C.45:14-15.1 through 45:14-15.4); section 2 of
11 P.L.1953, c.329 (C.45:14-16.1); sections 1 and 2 of P.L.1949, c.93
12 (C.45:14-26.1 and 45:14-26.2); and P.L.1948, c.105 (C.45:14-36.1
13 through 45:14-36.4) are repealed.

14
15 43. This act shall take effect immediately.

16

17

18 STATEMENT

19

20 This bill enacts the "New Jersey Pharmacy Practice Act" and
21 repeals the current law providing for the regulation and licensure of
22 pharmacists.

23 The bill reenacts most of the provisions of the current law with
24 some changes and includes some new provisions, such as providing
25 that pharmacists may be engaged in the management of a patient's
26 drug, biological and device-related health care needs pursuant to a
27 written protocol in collaboration with a licensed physician and
28 providing that any person located outside the United States shall be
29 prohibited from shipping, mailing, distributing or delivering to any
30 person in this State legend drugs or devices approved by the federal
31 Food and Drug Administration and available in the United States
32 pursuant to a prescription. The provisions of the current law requiring
33 utilization reviews, patient profiles and counseling and non-
34 reproducible, non-erasable safety paper New Jersey Prescription
35 Blanks are continued under the bill.

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 2598

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 12, 2003

The Senate Commerce Committee reports favorably, and with committee amendments, Senate Bill No. 2598.

This bill, as amended, enacts the "New Jersey Pharmacy Practice Act" and repeals the current law providing for the regulation and licensure of pharmacists.

The bill reenacts most of the provisions of the current law with some changes, and includes some new provisions, such as providing that pharmacists may be engaged in the management of a patient's drug, biological and device-related health care needs pursuant to a written protocol in collaboration with a licensed physician. Another new provision requires that pharmacies located in another state that solicit, advertise, ship, mail or deliver drugs pursuant to a valid prescription into this State must register with the board and file certain information with the board, pay an annual registration fee not exceeding \$500, and maintain a certain level of customer service, such as a toll-free telephone service. The provisions of the current law requiring utilization reviews, patient profiles and counseling and non-reproducible, non-erasable safety paper New Jersey Prescription Blanks are continued under the bill.

The New Jersey State Board of Pharmacy and the State Board of Medical Examiners, through joint regulations, shall establish specific requirements that are to be included in any written protocol between a physician and pharmacist. The bill states that any such written protocol is to be directed on a voluntary basis by a patient's physician. Each collaborative drug therapy management shall be between a single patient's specific physician and the patient's pharmacist or pharmacy and address that patient's specific condition, disease or diseases. A pharmacist shall administer a prescription drug directly to a patient: only with appropriate education or certification, as determined by the board and the State Board of Medical Examiners; only for the treatment of a disease for which a nationally certified program is in effect, or as determined by the board; and only if utilized for the treatment of that disease for which the drug is prescribed or indicated or for which the collaborative drug therapy management permits.

Other than for pediatric immunizations, a pharmacist may administer drugs in immunization programs and programs sponsored by governmental agencies that are not patient specific.

The provisions of the bill regulating collaborative drug therapy management shall not apply to any pharmacist practicing in any hospital, provided that prescribing within these institutions takes place under the guidance of a pharmacy and therapeutics committee in accordance with procedures as determined by regulations of the board and the State Board of Medical Examiners.

A pharmacist may dispense a prescription in a different dosage form than originally prescribed if the dosage form dispensed has the appropriate release rate. A pharmacist must notify the prescriber of the change made in the dosage form in the filling of the prescription no later than 48 hours following the dispensing of the prescription.

The committee amended the bill to make certain clarifying and technical amendments, to provide the rules for collaborative practice shall be jointly promulgated by the New Jersey State Board of Pharmacy and the State Board of Medical Examiners and to eliminate the provisions allowing the board to regulate out-of-state and foreign pharmacies.