Pharmacy Practice

This Act comprehensively updates and also expands the laws governing the practice of pharmacy in the state, by individual pharmacists, retail pharmacies, and health care systems in the state. It requires out-of-state pharmacies doing business in this State to register with the state, and meet certain other public safety and consumer-oriented requirements. Perhaps most significantly, the Act expands the authorized practice of pharmacy to include collaborative drug therapy management, a cooperative agreement between a doctor and a pharmacist, with the patient's consent, in which the pharmacist may take a more active role in the management of the patient's prescription drug therapy than is currently permissible. The bill also codifies the role of the pharmacist technician and defines the activities that may be performed by pharmacy technicians.

Submitted as:
New Jersey
Chapter 280
Status: Enacted into law in 2004.

Suggested State Legislation

(Title, enacting clause, etc.)

Section 1. [*Short Title*.] This Act shall be known and may be cited as "The Pharmacy Practice Act."

Section 2. [*Legislative Findings*.]

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

b. It is the purpose of this Act to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy, the licensure of pharmacists and the permitting, control and regulation of all pharmacy practice sites in this State that engage in the practice of pharmacy.

Section 3. [*Definitions Relative to Pharmacists*.] As used in this Act:

"Administer" means the direct application of a drug to the body of a patient or research subject by subcutaneous, intramuscular or intradermal injection, inhalation or ingestion by a pharmacist engaged in collaborative practice or in accordance with regulations jointly promulgated by the [board] and the [State Board of Medical Examiners].

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

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

"Board of Pharmacy" or "board" means the [State Board of Pharmacy].

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

"Collaborative drug therapy management" means a written protocol directed on a voluntary basis by a patient's physician, with the patient's consent, that is between a patient's physician who is treating the patient for a specific disease and a pharmacist for cooperative management of a patient's drug, biological and device-related health care needs, which shall be conducted in accordance with regulations jointly promulgated by the [board] and the [State Board of Medical Examiners] and shall only include the collecting, analyzing and monitoring of patient data; ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written protocol; ordering of clinical tests based on the standing orders of a physician as set forth in the written protocol, provided those laboratory tests are granted waived status in accordance with the provisions of the [insert citation], and are for the treatment of a disease state identified jointly by the board and the [State Board of Medical Examiners] as subject to collaborative drug therapy management; modifying, continuing or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms or route of administration. The interpretation of clinical or laboratory tests under a written protocol may only be performed by a pharmacist in direct consultation with a physician.

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

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

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

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

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

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

"Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Pharmacist in collaborative practice" means a pharmacist engaged in the collaborative drug therapy 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 in accordance with the regulations jointly promulgated by the [board] and the [State Board of Medical Examiners].

"Pharmacy practice site" means any place in this State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician.

"Pharmacy technician" means an individual working in a pharmacy practice site who, under the immediate supervision of a pharmacist, assists in pharmacy activities as permitted by this section of this Act and the rules and regulations of the [board] that do not require the professional judgment of a pharmacist.

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

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

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

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

"Prescription drug" or "legend drug" means a drug which, under federal law, is required to be labeled prior to being delivered to the pharmacist, with either of the following statements: "Rx Only" or "Caution: Federal law restricts this drug to use by, or on the order of, a licensed

veterinarian" or is required by any applicable federal or state law, rule or regulation to be dispensed pursuant to a prescription drug order or is restricted to use by a practitioner only.

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

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

Section 4. [*Powers, Duties, Authority of Board*.]

The [board] shall enforce the provisions of this Act. The [board] shall have all of the duties, powers and authority specifically granted by or necessary for the enforcement of this Act, as well as such other duties, powers and authority as it may be granted from time to time by applicable law.

Section 5. [*Board Membership, Terms, Vacancies*.]

a. The [board] shall consist of [eleven members], [two] of whom shall be public members and one of whom shall be a [State executive department] member appointed pursuant to the provisions of [insert citation]. Each of the remaining [eight] members shall be pharmacists. Each pharmacist member shall have at least [five years] of experience in the practice of pharmacy in this State after licensure, and shall at the time of appointment and throughout their tenure: be currently licensed and in good standing to engage in the practice of pharmacy in this State, and be actively engaged in the practice of pharmacy in this State.

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

c. Except for the members first appointed, members of the [board] shall be appointed for a term of [five years], except that members of the [board] who are appointed to fill vacancies which occur prior to the expiration of a former member's full term shall serve the unexpired portion of that term. The terms of the members of the [board] shall be staggered, so that the terms of no more than [three] members shall expire in any year. Each member shall serve until a successor is appointed and qualified. The present members of the [board] appointed pursuant to [insert citation] shall serve the balance of their terms. Any present [board] member appointed initially for a term of less than [five years] shall be eligible to serve for [two additional] full terms. No member of the [board] shall serve more than [two consecutive] full terms. The completion of the unexpired portion of a full term shall not constitute a full term for purposes of this subsection.

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

Section 6. [*Election of Officers*.]

a. The [board] shall annually elect from among its members a [president] and [vice-president].

b. The position of [executive director] shall be held by a pharmacist licensed in this State. The [executive director] shall be responsible for the performance of the administrative functions of the [board] and those other duties that the [board] may direct.

Section 7. [*Compensation*.] Each member of the [board] shall receive compensation pursuant to [insert citation] of [$150] per day for each day on which the member is engaged in performance of the official duties of the [board], and shall be reimbursed for all reasonable and necessary expenses incurred in connection with the discharge of those official duties.

Section 8. [*Board Meetings*.] The [board] shall meet at least [once] every month to transact its business. The [board] shall meet at those additional times that it may determine. Additional meetings may be called by the [president of the board] or by [two-thirds] of the members of the [board].

Section 9. [*Rules, Regulations; Joint Rules*.] The [board] shall make, adopt, amend and repeal those rules and regulations necessary for the proper administration and enforcement of this act. Those rules and regulations shall be promulgated in accordance with the [insert citation]. Rules pertaining to collaborative drug therapy management and administration of drugs by pharmacists shall be jointly promulgated by the board and the [State Board of Medical Examiners].

Section 10. [*Responsibilities of Board.*]

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

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

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

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

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

(5) The establishment of requirements jointly promulgated with the [State Board of Medial Examiners] for pharmacists to administer drugs directly to patients;

(6) The enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this State, and the suspension, revocation, failure to renew or restriction of licenses to engage in the practice of pharmacy pursuant to the provisions of [insert citation];

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

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

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

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

(11) The inspection of any pharmacy practice site at all reasonable hours for the purpose of determining if any provisions of the laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The [board], its officers, inspectors and representatives shall cooperate with all agencies charged with the enforcement of the laws of the

United States, of this State, and of all other states relating to drugs, devices and the practice of pharmacy;

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

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

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

(15) The prescribing or changing of the fees for examinations, certifications, licensures, renewals and other services performed pursuant to [insert citation] and this Act.

b. The [board] shall have those other duties, powers and authority as may be necessary to the enforcement of this Act and to the enforcement of rules and regulations of the [board], which may include, but not be limited to, the following:

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

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

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

(4) The collection of professional demographic data;

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

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

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

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

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

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

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

c. (1) The [board] may place under seal all drugs, biologicals, radio pharmaceuticals or devices that are owned by or in the possession, custody or control of a licensee or permit holder at the time his license or permit is suspended or revoked or at the time the board refused to renew his license. Except as otherwise provided in this section, drugs, biologicals, radio pharmaceuticals or devices that are sealed pursuant to this paragraph shall not be disposed of until appeal rights under the [insert citation] have expired, or an appeal filed pursuant to that act

has been determined. The court, involved in an appeal filed pursuant to the [insert citation], may order the [board], during the pendency of the appeal, to sell sealed drugs, biologicals and radio pharmaceuticals that are perishable. The proceeds of a sale shall be deposited with the court.

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

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

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

d. Except as otherwise provided to the contrary, the [board] shall exercise all of its duties, powers and authority in accordance with the [insert citation].

Section 11. [*Licensure Required For Pharmacist*.]

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

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

c. Practitioners authorized under the laws of this State to compound drugs and to dispense drugs directly to their patients in the practice of their respective professions shall meet the standards established by their respective licensing boards with respect to storage, handling, security, counseling, labeling, packing and record keeping requirements for the dispensing of drugs, or if no such standards exist, the same storage, handling, security, counseling, labeling, packaging and record keeping requirements for the dispensing of drugs applicable to pharmacists.

Section 12. [*Application For License; Requirements*.] To obtain a license to engage in the practice of pharmacy, the applicant shall:

(1) Have submitted a written application in the form prescribed by the [board];

(2) Have attained the age of [18 years];

(3) Be of good moral character;

(4) Have graduated and received a professional degree from a college or school of pharmacy that has been approved by the [board];

(5) Have completed an internship or other program that has been approved by the [board], or demonstrated to the [board's] satisfaction experience in the practice of pharmacy which meets or exceeds the minimum internship requirements of the [board];

(6) Have successfully passed an examination or examinations as determined by the [board]; and

(7) Have paid the fees specified by the [board] for the examination and any related materials, and have paid for the issuance of the license.

Section 13. [*Examination for Licensure*.] The examination for licensure shall measure the competence of the applicant to engage in the practice of pharmacy. The [board] may employ, cooperate and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have successfully passed the examination.

Section 14. [*Practical Experience, Requirements*.]

a. All applicants for licensure by examination shall obtain practical experience in the practice of pharmacy under terms and conditions determined by the [board].

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

Section 15. [*Licensure for Pharmacist Currently Licensed in Another Jurisdiction*.]

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

(1) Have submitted a written application in the form prescribed by the [board];

(2) Have attained the age of [18 years];

(3) Have good moral character;

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

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

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

(7) Have paid the fees specified by the [board];

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

(9) Have met any other requirements as established by the [board] by regulation.

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

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

Section 16. [*Continuing Pharmacy Education*.]

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

b. The [board] shall:

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

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

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

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

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

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

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

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

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

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

Section 17. [*Use of {State} Prescription Blanks*.]

a. A practitioner practicing in this State shall use non-reproducible, non-erasable safety paper [state] Prescription Blanks bearing that practitioner's license number whenever the

practitioner issues prescriptions for controlled dangerous substances, prescription legend drugs or other prescription items. The prescription blanks shall be secured from a vendor approved by the [Division of Consumer Affairs in the Department of Law and Public Safety].

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

Section 18. [*Health Care Facility Prescriptions*.]

a. Prescriptions issued by a health care facility licensed pursuant to [insert citation] shall be written on non-reproducible, non-erasable safety paper [state] Prescription Blanks. The prescription blanks shall be secured from a vendor approved by the [Division of Consumer Affairs in the Department of Law and Public Safety]. The [state] Prescription Blanks shall bear the unique provider number assigned to that health care facility for the issuing of prescriptions for controlled dangerous substances, prescription legend drugs or other prescription items.

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

Section 19. [*Requirements for Prescription to be Filled*.] A prescription issued by a practitioner or health care facility licensed in [this State] shall not be filled by a pharmacist unless the prescription is issued on a [state] Prescription Blank bearing the practitioner's license number or the unique provider number assigned to a health care facility.

Section 20. *[Transmission of Prescription by Telephone, Electronic Means, CDS Requirements*.]

a. Nothing contained in this Act shall preclude a practitioner from transmitting to a pharmacist by telephone or electronic means a prescription, as otherwise authorized by law, if that practitioner provides the practitioner's Drug Enforcement Administration registration number and the practitioner's license number, or any other federally identified number, as appropriate, to the pharmacist at the time the practitioner transmits the prescription.

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

Section 21. [*Format for {State} Prescription Blanks*.] The [Division of Consumer Affairs in the Department of Law and Public Safety] shall establish the format for uniform, non-reproducible, non-erasable safety paper prescription blanks, to be known as [state] Prescription Blanks, which format shall include an identifiable logo or symbol that will appear on all prescription blanks. The [division] shall approve a sufficient number of vendors to ensure

production of an adequate supply of [state] Prescription Blanks for practitioners and health care facilities statewide.

Section 22. [*Different Dosage Form, Conditions*.] A pharmacist may dispense a prescription in a different dosage form than originally prescribed if the pharmacist notifies the prescriber no later than [48 hours] following the dispensing of the prescription, provided the dosage form dispensed has the appropriate drug release rate.

Section 23. [*Requirements for Collaborative Practice*.]

a. In establishing requirements for pharmacists to engage in collaborative practice as provided in paragraph (4) of subsection a. of section 10 of this Act, the [board] shall include in these requirements, but not be limited to, provisions that any written protocol between a physician and pharmacist:

(1) is agreed to by both the physician and the pharmacist with the consent of the patient;

(2) identifies, by name and title, each physician and each pharmacist who is permitted to participate in a patient's collaborative drug therapy management;

(3) specifies the functions and responsibilities the pharmacist will be performing;

(4) is available at the practice sites of the pharmacist and physician and made available at each site to the patient;

(5) is initiated and utilized at the sole discretion of the physician for a specific patient;

(6) may be terminated at any time by either party by written documentation;

(7) establishes when physician notification is required, the physician chart update interval, and an appropriate time frame within which the pharmacist must notify the physician of any change in dose, duration or frequency of medication prescribed;

(8) remains in effect for a period not to exceed [two years] upon the conclusion of which, or sooner, the parties shall review the protocol and make a determination as to its renewal, modification or termination; and

(9) establish the means by which the patient will be advised of the right to elect to participate in and withdraw from the collaborative drug therapy management.

Section 24. [*Collaborative Drug Therapy Management*.]

a. 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.

b. No collaborative drug therapy management shall include, without the prior consent of the patient and the patient's physician who has signed the protocol, therapeutic interchange at the time of dispensing, provided that written confirmation of this prior consent, which may be by electronic means, shall be obtained pursuant to record keeping guidelines to be established by regulation jointly promulgated by the [board] and the [State Board of Medical Examiners].

Section 25. *[Administration of Prescription Medication Directly to Patient, Immunizations*.]

a. No pharmacist shall administer a prescription medication directly to a patient without appropriate education or certification, as determined by the [board] in accordance with the requirements set forth in the rules jointly promulgated by the [board] and the [State Board of Medical Examiners]. Such medication shall only be 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 medication is prescribed or indicated or for which the collaborative drug therapy management permits.

b. Notwithstanding any law, rule or regulation to the contrary, other than for pediatric immunizations, a pharmacist may administer drugs in immunization programs and programs sponsored by governmental agencies that are not patient specific provided the pharmacist is appropriately educated and qualified, as determined by the [board] in accordance with the requirements set forth in the rules jointly promulgated by the [board] and the [State Board of Medical Examiners].

Section 26. [*Inapplicability Relative to Collaborative Drug Therapy Management in Hospitals*.] The provisions of this Act regulating collaborative drug therapy management shall not apply to any pharmacist practicing in a 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 jointly promulgated by the [board] and the [State Board of Medical Examiners].

Section 27. [*Refusal of Application for Examination, Suspension, Revocation of Certificate; Procedure*.]

a. In addition to the provisions of [insert citation], the [board] may refuse an application for examination or may suspend or revoke the certificate of a licensed pharmacist upon proof satisfactory to the [board] that such licensed pharmacist is guilty of grossly unprofessional conduct and the following acts are hereby declared to constitute grossly unprofessional conduct for the purpose of this Act:

(1) Paying rebates or entering into an agreement for payment of rebates to any physician, dentist or other person for the recommending of the services of any person.

(2) The providing or causing to be provided to a physician, dentist, veterinarian or other person authorized to prescribe, prescription blanks or forms bearing the pharmacist's or pharmacy's name, address or other means of identification.

(3) The claiming of professional superiority in the compounding or filling of prescriptions or in any manner implying professional superiority which may reduce public confidence in the ability, character or integrity of other pharmacists.

(4) Fostering the interest of one group of patients at the expense of another which compromises the quality or extent of professional services or facilities made available.

(5) The distribution of premiums or rebates of any kind whatsoever in connection with the sale of drugs and medications provided, however, that trading stamps and similar devices shall not be considered to be rebates for the purposes of this act and provided further that discounts, premiums and rebates may be provided in connection with the sale of drugs and medications to any person who is [60 years] of age or older.

(6) Advertising of prescription drug prices in a manner inconsistent with rules and regulations promulgated by the [Director of the Division of Consumer Affairs], except that no advertising of any drug or substance shall be authorized unless the [Commissioner of Health and Senior Services] shall have determined that the advertising is not harmful to public health, safety and welfare.

(7) Engaging in activities beyond the scope of a collaborative drug therapy management agreement.

b. Before a certificate shall be refused, suspended or revoked, the accused person shall be furnished with a copy of the complaint and given a hearing before the [board]. Any person whose certificate is so suspended or revoked shall be deemed an unlicensed person during the period of such suspension or revocation, and as those shall be subject to the penalties prescribed

in this act, but that person may, at the discretion of the [board], have his certificate reinstated at any time without an examination, upon application to the [board]. Any person to whom a certificate shall be denied by the board or whose certificate shall be suspended or revoked by the [board] shall have the right to review that action by appeal to the [Appellate Division of the Superior Court] in lieu of prerogative writ.

Section 28. [*Drug Utilization Review, Requirements*.]

a. A pharmacist shall conduct a drug utilization review before each new medication is dispensed or delivered to a patient.

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

c. A pharmacist shall exercise independent professional judgment as to whether or not to dispense or refill a prescription or medication order. In determining to dispense or refill a prescription or medication order, the decision of the pharmacist shall not be arbitrary but shall be based on professional experience, knowledge or available reference materials.

Section 29. [*Provision of Counseling on New Prescriptions*.] A pharmacist or his designee shall offer to provide counseling to any person who presents a new prescription in a manner as determined pursuant to criteria established by the [board].

Section 30. [*Patient Profile System*.]

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

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

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

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

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

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

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

(6) The number or designation identifying the prescription;

(7) The practitioner's name;

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

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

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

c. The information obtained shall be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records, and may be considered by the pharmacist in the exercise of his professional judgment concerning both the

offer to counsel and content of counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

Section 31. [*Issuance of Permit for Pharmacy Practice Sites*.]

a. All pharmacy practice sites in this State, which engage in the practice of pharmacy in [this State], shall be issued a permit by the [board], and shall annually renew their permit with the [board]. If operations are conducted at more than one location, each location shall be issued a permit by the [board] for the dispensing of medicine.

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

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

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

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

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

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

Section 32. [*Permit Application Procedures*.]

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

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

c. The [board] shall specify, by rule or regulation, minimum standards for any pharmacy practice site within this State. Pharmacy practice sites located in [this State] shall be operated at all times under the immediate supervision of a pharmacist licensed to practice in this State.

d. Permits issued by the [board] pursuant to this Act shall not be transferable or assignable without the approval of the [board].

Section 33. [*Licensure Required for Use of Certain Terms*.] No person shall carry on, conduct or transact business under a name which contains as a part thereof the words "pharmacist," "pharmacy," "apothecary," "apothecary shop," "druggist," "drug" or any word or words of similar or like import, or in any manner by advertisement, circular, poster, sign or otherwise describe or refer to the place of business by the terms "pharmacy," "apothecary," "apothecary shop," "chemist's shop," "drug store," "drugs" or any word or words of similar or like import unless the place of business is a currently licensed pharmacy practice site operated or managed at all times by a pharmacist.

Section 34. [*Sale of Non-Prescription Drugs, Devices Unaffected*.] This Act shall not prohibit, restrict or otherwise interfere with the sale of non-prescription drugs and devices at places other than a pharmacy practice site or by persons in this State who are not licensed pharmacists.

Section 35. [*Registration of Out-Of-State Pharmacies; Requirements*.]

a. Any pharmacy located in another state which ships, mails, distributes or delivers in any manner, legend drugs or devices pursuant to a prescription into this State, shall register with the [board] and provide the [board] with the following information:

(1) The location, names and titles of all principal corporate officers of the pharmacy. A report containing this information shall be made on an annual basis and within [30 days] after any change of office or corporate officer; and

(2) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the [board] pursuant to this section. As a prerequisite to registering with the [board], the pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located. The annual registration fee shall be established by the [board] and shall not exceed [$500] annually.

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

Section 36. [*Report of Certain Occurrences*.]

a. All licensed pharmacy practice sites shall report to the [board] the occurrences of any of the following:

(1) Closing of the pharmacy practice site;

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

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

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

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

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

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

Section 37. [*Permit Required for Operation of Pharmacy Practice Site*.]

a. No pharmacy practice site shall operate until it has been issued a permit by the [board].

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

(1) Findings by the [board] that any conduct of the permit holder or applicant violates any federal, State or local laws or regulations relating to the practice of pharmacy;

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

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

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

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

(6) Dealing with drugs or devices that are known or should have been known as stolen drugs or devices;

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

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

(9) Violation of any of the provisions of the [state controlled substance Act] by the applicant, permit holder or occurring at the pharmacy practice site; or

c. Reinstatement of a permit that has been suspended or restricted by the [board] may be granted in accordance with the procedures specified by the [board].

Section 38. [*Compliance With Federal Law, Standards*.] Pharmacists and pharmacies shall comply with the provisions of the federal Standards of Practice of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

Section 39. [*Immunity from Civil Damages for Reports of Alleged Misconduct*.] A person who in good faith and without malice provides to the [board] any information concerning any act by a pharmacist licensed by the [board] which the person has reasonable cause to believe involves misconduct that may be subject to disciplinary action by the [board], or any information relating to such conduct requested by the [board] in the exercise of its statutory responsibilities or which may be required by statute, shall not be liable for civil damages in any cause of action arising out of the provision of such information or services.

Section 40. [*Currently Licensed Pharmacists, Practice Sites*.]

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

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

Section 41. [*Prior Regulations Unaffected*.] This Act shall not affect the orders, rules and regulations regarding the practice of pharmacy made or promulgated by the [board] created pursuant to [insert citation] prior to the effective date of this Act.

Section 42. [*Pharmacy Technicians, Conditions*.]

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

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

(2) Data entry;

(3) Label preparation; and

(4) Counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system.

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

c. Pharmacy technicians shall not:

(1) Receive new verbal prescriptions;

(2) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(3) Verify dosage and directions;

(4) Engage in prospective drug review;

(5) Provide patient counseling;

(6) Monitor prescription usage;

(7) Override computer alerts without first notifying the pharmacist;

(8) Transfer prescriptions from one pharmacy to another pharmacy; or

(9) Violate patient confidentiality.

d. Except as provided in subsection e. of this section, a pharmacist shall not supervise more than [two] pharmacy technicians.

e. A pharmacy that wishes to employ a licensed pharmacist to pharmacy technician ratio greater than established in accordance with subsection d. of this section, shall:

(1) Establish written job descriptions, task protocols and policies and procedures that pertain to the duties performed by the pharmacy technician;

(2) Ensure and document that each pharmacy technician pass the National Pharmacy Technician Certification Examination or a [board] approved certification program and fulfill the requirements to maintain this status, or complete a program which includes a testing component and which has been approved by the [board] as satisfying the criteria as set forth in subsection f. of this section;

(3) Ensure that each pharmacy technician is knowledgeable in the established job descriptions, task protocols and policies and procedures in the pharmacy setting in which the technician is to perform his duties;

(4) Ensure that the duties assigned to any pharmacy technician do not exceed the established job descriptions, task protocols and policies and procedures;

(5) Ensure that each pharmacy technician receives in-service training before the pharmacy technician assumes his responsibilities and maintain documentation thereof;

(6) Require and maintain on site a signed patient confidentiality statement from each technician;

(7) Provide immediate personal supervision; and

(8) Provide the [board], upon request, with a copy of the established job descriptions, task protocols and policies and procedures for all pharmacy technician duties.

f. If the pharmacist to pharmacy technician ratio is greater than the ratio established in accordance with the provisions of subsection d. of this section, the pharmacy shall maintain a policy and procedure manual with regard to pharmacy technicians, which shall include the following:

(1) Supervision by a pharmacist;

(2) Confidentiality safeguards of patient information;

(3) Minimum qualifications;

(4) Documentation of in-service education or ongoing training and demonstration of competency, specific to practice site and job function;

(5) General duties and responsibilities of pharmacy technicians;

(6) Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

(7) Functions related to prescription processing;

(8) Functions related to prescription legend drug and controlled dangerous substance ordering and inventory control;

(9) Prescription refill and renewal authorization;

(10) Procedures dealing with documentation and records required for controlled dangerous substance and prescription legend drugs;

(11) Procedures dealing with medication errors;

(12) Pharmacy technician functions related to automated systems;

(13) Functions that may not be performed by pharmacy technicians; and

(14) A form signed by the pharmacy technician which verifies that the manual has been reviewed by the technician.

g. The pharmacist in charge shall review the policy and procedure manual at least every [two years] and, if necessary, amend the manual as needed. Documentation of the review shall be made available to the [board] upon request.

h. Pharmacy technicians shall wear an identification tag, which shall include at least their first name, the first initial of their last name and title.

i. On pharmacy permit renewal applications, the pharmacy shall list the name and address of all pharmacy technicians which it currently employs.

j. When pharmacy technicians are engaged in any activities permitted in accordance with the provisions of this section, the licensed pharmacists on site shall be responsible for these activities.

Section 43. [*Severability*.] [Insert severability clause.]

Section 44. [*Repealer*.] [Insert repealer clause.]

Section 45. [*Effective Date.*] [Insert effective date.]