

(H. B. 4248)
(Conference)

(No. 247)

(Approved September 3, 2004)

AN ACT

To regulate the exercise of the pharmacist profession and the pharmacy technician occupation; to create the Puerto Rico Board of Pharmacy, establish its organization and functions; regulate the manufacture, distribution and dispensing of drugs in the Commonwealth of Puerto Rico; to regulate the interchange for bioequivalent drugs in Puerto Rico; repeal Act No. 282 of May 15, 1945, as amended; repeal subsections (e), (f), (h), (i) and (l) of Section 3, Sections 21, 22, 23, 24, 25, 27, 28, and 29, amend Section 35, and amend Section 36 of Act No. 11 of June 23, 1976, as amended; to fix penalties; and for other purposes.

STATEMENT OF MOTIVES

The purpose of this Act is to promote and protect the public health, safety, and welfare. The Act strengthens the Puerto Rico Board of Pharmacy, the body responsible for the regulation of the pharmacist profession and establishes a more specific definition of the responsibilities and functions of the pharmacist and the pharmacy technician. Furthermore, this Act creates the Medication and Pharmacy Division, as an administrative unit of the Department of Health, for a more effective monitoring of the phases of manufacture, distribution, dispensing drugs and interchange for bioequivalent drugs in Puerto Rico.

Act No. 11 of June 23, 1976, as amended, is hereby amended to transfer to this Act the provisions that regulate the interchange for bioequivalent drugs by establishing mechanisms to expedite the process.

Act No. 282 of May 15, 1945, as amended, is hereby repealed and the essential provisions compatible with modern concepts and approaches in the regulation of the profession of pharmacy, of the rendering of pharmaceutical services, and of the procedures and of the establishments engaged in the dispensation of medications in the Commonwealth of Puerto Rico.

BE IT ENACTED BY THE LEGISLATURE OF PUERTO RICO:

CHAPTER I

GENERAL PROVISIONS

Section 1.01 – Title

Section 1.02 – Purpose

Section 1.03 – Definitions

Section 1.01.—Title.—

This Act shall be known as the “Puerto Rico Pharmacy Act.”

Section 1.02.—Purpose.—

The purpose of this Act is to promote, preserve and protect the public health, safety, and welfare through the effective control and regulation of the practice of pharmacy, and the licensing, control and regulation of establishments and persons who manufacture, distribute, dispense, and sell drugs and devices used for diagnosis, treatment, or prevention of diseases in the Commonwealth of Puerto Rico. This Act does not regulate or affect in any way the marketing of drugs via mail from the United States or foreign countries to the territorial jurisdiction of the Commonwealth of Puerto Rico.

Section 1.03.—Definitions.—

For the purposes of this Act, the following terms and phrases shall have the meaning stated below:

(a) “Administration of Drugs” – an action through which any drug dose is used or applied in or to a human or animal by injection, inhalation, ingestion, or any other means, with the authorization and in accordance with the indications or prescription made by a physician, odontologist, dentist, podiatrist, or in the case of animals, by a veterinarian authorized to practice the profession in Puerto Rico.

(b) “Representative Agent” – any person authorized and registered with the Secretary to represent any medication manufacturer or distributor in the marketing thereof, without being involved in the storage, distribution, or dispensation of the same.

(c) “Device” – any object, article, or instrument designed, prepared or made to be used in the diagnosis, cure, mitigation, treatment, or prevention of diseases of a human being or an animal, pursuant to the laws of Puerto Rico and the United States.

(d) “Drug Cabinet” – Deposit of limited quantities of drugs in institutions, medical offices, or in Category III Ambulance Stations intended solely for their administration to patients in such institution, medical office, or ambulance, or to be used in educational institutions for educational or research purposes, thus prohibiting their dispensing or delivery for their subsequent use by patients. The definition above does not include first aid kits or medication kits required by existing Federal and state labor laws and regulations, such as the Occupational Safety and Health Act (OSHA) according to the terms required by federal or state legislation. Any drugs in

excess to the quantities required by federal or state laws shall be subject to the drug cabinet regulations directed in this Act.

(e) “College of Pharmacists of Puerto Rico” – the quasi-public corporation created with said name by Act No. 243 of May 15, 1938, as amended, which groups all pharmacists authorized to practice the profession of pharmacy in Puerto Rico.

(f) “Compounding” – the preparation, unseasonable mixing, or reconstitution of a drug based on the physician-patient-pharmacist relationship in compliance with the requirements established by the Board of Pharmacy and any other regulatory agencies.

(g) “Pharmaceutical Care or Pharmaceutical Assistance” – the practice of the profession of pharmacy centered in the patient and oriented to results that require the pharmacist to work together with the patient and other health care providers, to promote health, to prevent diseases, and ensure that the pharmacotherapy regime of the patient to be safe and effective, with the purpose of contributing to the patient’s achievement of an optimum quality of life in terms of his/her health.

(h) “Department” – the Department of Health of the Commonwealth of Puerto Rico and all its programs, offices, dependencies, and divisions attached thereto.

(i) “Dispensing or Dispatch” – the action carried out by a pharmacist of receiving, verifying, evaluating and interpreting a prescription, choosing or compounding, packaging, labeling and delivering of drugs or devices directly to a patient or his/her authorized representative, including providing counseling and advice to the patient on the adequate use thereof. Provided, that the pharmacy technician, the pharmacy technician intern, as well as the pharmacist intern may carry out some of these functions under

the supervision of the pharmacist, except for verifying the prescription and orienting the patient. In the case of drugs for animals, these shall be processed in agreement to the provisions of Act 194 of August 4, 1979, as amended.

(j) “Distribution” – the wholesale sale or distribution of drugs to establishments authorized and registered by the Secretary, as provided by this Act.

(k) “Wholesale Medications Distributor” – any person duly authorized and registered by the Secretary who is engaged in the wholesale distribution of prescription drugs to authorized establishments, including but without being limited to manufacturers, repackagers, own or private label distributors, wholesaler drugstores, intermediaries, agents, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and independent wholesale drug trader, and retail pharmacies that conduct wholesale distributions.

(l) “Nonprescription Drug Wholesaler” – any person duly authorized and registered by the Secretary for the wholesale sale and distribution of nonprescription drugs, to authorized establishments pursuant to the provisions of this Act.

(m) “Nonprescription Drug Retailer” – any person duly authorized and registered by the Secretary for the retail sale of nonprescription drugs, pursuant to the provisions of this Act.

(n) “Veterinary Drug Retailer” – any person duly authorized and registered for the wholesale sale of veterinary drugs, as provided by this Act.

(o) “Nonprescription Veterinary Drug Retailer” – any person duly authorized and registered for the retail sale of nonprescription veterinary drugs, as provided by this Act.

(p) “Drug and Pharmacy Division” – administrative unit attached to the Office of the Deputy Secretary for Health Facility Regulation and Accreditation of the Department of Health.

(q) “Drug” – any substance of animal, vegetable, mineral or synthetic origin, or combination thereof, (1) recognized in the official compendium of the United States Pharmacopoeia, the National Formulary, or the Homeopathic Pharmacopoeia of the United States; (2) or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, injury, or any other condition that affects the health of human beings or other animals; (3) or (other than food) intended to affect or assess the structure or other function of the body of humans or animals; (4) or the component of any of the above.

(r) “Wholesaler Drugstore” – any establishment authorized and registered pursuant to this Act for the wholesale sale drugs, devices, and products, including those related to veterinary medicine.

(s) “Patient Pharmacy Record” – information of the patient that is electronically collected or otherwise organized to allow pharmacists to identify any drug-related problems and document their interventions and the results obtained for the protection of the health, safety and welfare of the patient.

(t) “Pharmacist” – any person duly authorized pursuant to this Act to practice the profession of pharmacy in Puerto Rico.

(u) “Inspector Pharmacist” – a pharmacist official of the Department of Health designated and authorized to oversee compliance with all the requirements established in this Act by the establishments carrying out any of the activities set forth herein.

(v) “Preceptor Pharmacist” – a pharmacist authorized by the Board of Pharmacy to supervise the internship training of a pharmacist intern or a pharmacy technician intern.

(w) “Head Pharmacist” – a pharmacist registered as a head pharmacist in the records of the Department of Health, and who is responsible for overseeing faithful compliance with the provisions of this Act and any other laws applicable to the manufacture, distribution, and dispensation of drugs. In cases of head pharmacists in the pharmaceutical industry, the head pharmacist shall be understood to be the pharmacist in a pharmaceutical enterprise whose name is registered as such in the records of the Department of Health. He/she shall be responsible, as member of a multidisciplinary team, of overseeing faithful compliance with the provisions of this Act and any other laws applicable to the manufacture, packaging, and distribution of drugs in Puerto Rico.

(x) “Pharmacy” – a health service establishment, physically located within the jurisdiction of Puerto Rico, authorized and registered pursuant to the provisions of this Act, to be engaged in the rendering of pharmaceutical services, that include: dispensation of prescription drugs, nonprescription drugs, devices, and other articles related to health; the rendering of pharmaceutical care, and other services within the pharmacist’s functions established by this Act. Provided, that the pharmacy shall offer the public other legally tradeable products and services business, according to the applicable laws.

(y) “Community Pharmacy” – any pharmacy engaged in the rendering of pharmaceutical services to outpatients and the general public.

(z) “Institutional Pharmacy” – any pharmacy engaged in the rendering of pharmaceutical services to patients admitted into a health care service institution or facility.

(aa) “Pharmaceutical Industry” – the industry engaged in the manufacture, marketing, and distribution of drugs.

(bb) “Confidential Information” – any information obtained in the pharmacist-patient relation, which is expected not to be released, including the protected health information of the patient.

(cc) “Internship” – the practical training period required of a Pharmacy Intern or a Pharmacy Technician Intern, as authorized by the Board of Pharmacy.

(dd) “Pharmacy Intern” – a candidate for a pharmacist license authorized by the Board of Pharmacy to receive practical training under the direct and immediate supervision of a preceptor pharmacist.

(ee) “Pharmacy Technician Intern” – a candidate for a certificate of pharmacy technician authorized by the Board of Pharmacy to receive practical training under the direct and immediate supervision of a preceptor pharmacist.

(ff) “Veterinary Facility” – a doctor’s office, dispensary, office, clinic, or diagnostic and treatment facility, hospital, veterinary outpatient clinic, or any other public or private institution in which veterinarians authorized to practice their profession in Puerto Rico render professional services.

(gg) “Board” – the Puerto Rico Board of Pharmacy created by this Act.

(hh) “Free Pharmacy Selection” – the right of the patient to select the pharmacy of his/her choice, voluntarily and without pressure from other persons or institutions.

(ii) “Manufacture” – the production, preparation, and processing of drugs, whether directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis to be used as drugs. It includes any packing or repackaging of the substances or labeling of its container.

(jj) “Medication or medicine” – any drug intended for use by humans or other animals in appropriate doses.

(kk) “Prescription Drug or Medication” – any drug that is required under the Puerto Rico or the United States laws to be dispensed by prescription, which shall be dispensed by a pharmacist in a pharmacy duly authorized and registered by the Secretary of Health; or in the case of veterinary drugs, these may also be dispensed by a veterinarian duly authorized to practice his/her profession in Puerto Rico.

(ll) “Nonprescription Drug or Medication” – any drug that, in accordance with the laws of Puerto Rico or the United States, may be dispensed without a prescription.

(mm) “Bioequivalent Drug” – those drugs classified by the Food and Drugs Administration (FDA) as therapeutically equivalent since they contain the same active ingredients, have the same strength, dosage and form of administration; and have comparable bioavailability.

(nn) “Radioactive Drug or Radiopharmaceutical” – A drug or medication that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons, including any non-radioactive

reagent kit or nuclide generator that is intended to be used in the preparation of such substance

(oo) “Veterinary Drug” – any drug indicating in its label that it is intended exclusively for use in the diagnosis, prevention, cure, relief, or treatments of diseases in animals.

(pp) “Prescription Veterinary Drug” – any drug indicating in its label that may be dispensed solely and exclusively by means of an order or prescription issued by an authorized veterinarian.

(qq) “Patient” – natural person who is the final consumer of the pharmaceutical services, or in the case of animals, is that with which a duly licensed veterinarian maintains a valid veterinarian-client-patient relationship under Act No. 194 of August 4, 1979, as amended.

(rr) “Person” – any natural or juridical person, regardless of its denomination or manner in which it is constituted.

(ss) “Prescribing Professional” – medicine doctor, physician, odontologist, dentist, podiatrist, or veterinarian authorized to practice the profession in Puerto Rico, who issues a prescription so that the patient with whom he/she maintains a valid professional relationship receives the drugs.

(tt) “Biological Product” – a drug derived from live organisms and its by-products, such as serums, vaccines, antigens, antitoxins and others.

(uu) “Protocol” – document to execute the written agreement between the physician or group of physicians and the pharmacist, following the guidelines established by the Board, authorizing the pharmacist to initiate or modify the pharmacotherapy of the patient to collaboratively manage the same.

(vv) “Radiopharmacy” – any pharmacy authorized and registered by the Secretary of Health engaged in the preparation and dispensation of radioactive drugs.

(ww) “Prescription” – original written order issued and signed by a medical doctor such as a physician, odontologist, dentist, podiatrist, or in the case of animals, by a veterinarian, in the normal course and legal exercise of his/her profession in Puerto Rico, in order for certain drugs or devices to be dispensed in compliance with the provisions of this Act. It shall be the obligation of the physician issuing the same to comply with the professional responsibility of a true physician-patient relationship.

(xx) “Pharmacy Counter” – space or area in a pharmacy devoted to dispensing prescription drugs and devices.

(yy) “Doctor-Patient Relationship” – It is that action through which a physician, as described in subsection (vv) above, assumes or has assumed the responsibility of performing an evaluation or clinical determination regarding the patient’s health. He/she determines the need for medical treatment based on the general or preliminary diagnosis of the medical condition which calls for said treatment and proves to be available for follow-up treatment in case of an adverse reaction or failure in the therapeutic regime. Being it understood that a valid professional relationship may not be established solely by phone or electronic means.

(zz) “Representative or Authorized Representative” – legal guardian, relative, or natural person of legal age, designated and identified, freely and willingly, by the patient to personally receive the pharmaceutical services on behalf of the patient, thus complying with the laws and regulations applicable to the confidentiality and privacy of the patient’s protected health information. In the case of animals, it shall be understood as

the representative or authorized representative of the holder of the prescription.

(aaa) “Secretary or Secretary of Health” – the Secretary of the Department of Health of the Government of Puerto Rico.

(bbb) “Pharmacy Technician” – any person duly authorized pursuant to this Act to practice the occupation of pharmacy technician in Puerto Rico. It includes any person, who at the time of the approval of this Act is authorized by the Board of Pharmacy to practice the occupation of pharmacy assistant, pursuant to Act No. 282 of May 15, 1945, as amended.

(ccc) “Electronic Transmission” – means the transmission of information through electronic means, including the digital transmission or the visual transmission of the exact image of a document of electronic equipment.

CHAPTER II

THE PROFESSION OF PHARMACY

Section 2.01 – Responsibilities of the Profession of Pharmacy

Section 2.02 – Functions of the Pharmacist

Section 2.03 – Responsibilities of the Pharmacy Technician Occupation

Section 2.04 – Functions of the Pharmacy Technician

Section 2.05 – Norms or Standards of the Practice of Pharmacy

Section 2.01.—Responsibilities of the Profession of Pharmacy.—

The profession of pharmacy is the health care profession geared towards the patient that has the social responsibility of providing pharmaceutical services to promote the health, safety, and welfare of the patient, prevent diseases and achieve optimum results in the use of drugs, as

integral part of health services. The profession of pharmacy also includes the active practice of the pharmacist in process of manufacture, storing, distribution, and dispensing of drugs.

Section 2.02.—Functions of the Pharmacist.—

In the practice of the profession of pharmacy, the pharmacist shall provide pharmaceutical services carrying out any of the following functions:

(a) Dispense drugs and devices by prescription, understanding that this function includes:

1. Receive, evaluate and interpret the prescription.
2. Complete the necessary information in the pharmaceutical record of the patient.
3. Determine and offer the patient the possibility of interchanging brand name drugs for generic drugs in agreement with the provisions of Section 5.03 of this Act.
4. Prepare, compound, pack, and label drugs in compliance with the applicable federal and state laws and regulations.
5. Verify the prescription against the medication and the patient's pharmacy record in order to identify, prevent, or solve drug-related problems.
6. Deliver any prescribed medication or device, after having advised the patient or his/her authorized representative on the same, provided that the advice on the medication entails the discussion of the information that in the judgment of the pharmacist is necessary and significant to optimize the pharmacotherapy of the patient. The delivery and advice shall be made on a person to person basis by the pharmacist, unless the patient expressly declines to receive such

advice. The advice shall be confidential and shall be complementary but not substituted by the written information.

(b) Offer advice to the patient or his/her authorized representative on the adequate use of nonprescription drugs or devices.

(c) Offer pharmaceutical care or assistance by performing the following process:

1. Obtain and interpret the information of the patient.
2. Identify, evaluate and prioritize medication-related problems.
3. Design an attention plan directed to achieving pharmacotherapy goals for the patient with the cooperation of the patient and the knowledge of his/her physicians;
4. Implement with the consent of the patient and knowledge of his/her physician and follow-ups on the same;
5. Document the entire process in the pharmaceutical record of the patient.

(d) Participate together with the patient and other health care providers in the decision-making process on the most adequate use of drugs, dosage, formulation, method of administration, dosage or administration regime.

(e) Manage the pharmacotherapy of the patient collaboratively with the physician or group of physicians following a protocol, without affecting the patient's free selection of the pharmacy that will dispense his/her drugs.

(f) Supervise technical and administrative functions delegated on the pharmacy technician.

(g) Supervise the internship of pharmacist interns or pharmacy technician interns as preceptor pharmacist.

(h) Act as the head pharmacist of a pharmacy, wholesaler drugstore, prescription drug wholesale distributor, or pharmaceutical industry manufacturing plant; provided, that this function shall be performed only in one establishment.

(i) Perform any other necessary functions, services, operations, transactions, incidental or as part of the functions mentioned above or that require or call for the science or the art of any branch of the pharmacy profession, study or training.

Section 2.03.—Responsibilities of the Pharmacy Technician Occupation.—

The Pharmacy Technician Occupation entails the responsibility to assist the pharmacist in technical and administrative functions regarding the dispensing of drugs and devices by prescription, pursuant to Section 2.02 (a), delegated by him/her. Upon performing such functions, the pharmacy technician shall always be under direct supervision of an authorized pharmacist.

Section 2.04.—Functions of the Pharmacy Technician.—

The Pharmacy Technician may perform, under direct supervision of the pharmacist, technical or administrative functions delegated to him/her by the pharmacist regarding the dispensing of prescription drugs and devices, and which do not require the professional judgment of the pharmacist for their performance. The Pharmacy Technician shall not verify prescriptions or advise the patient on the prescribed drugs. He/she shall neither perform any of the other functions of the pharmacist included in Articles 2.02 (b), (c), (d), (h), or (i) of this Act.

Section 2.05.—Norms or Standards of the Practice of Pharmacy.—

The Board, in collaboration with pharmaceutical professional organizations and educational institutions, shall adopt by regulations, the pharmacy practice guidelines, which shall include the norms or standards to provide pharmaceutical services of quality, based on the responsibilities and functions of the profession of pharmacy that are in harmony with the provisions of this Act.

CHAPTER III

PUERTO RICO BOARD OF PHARMACY

Section 3.01 – Puerto Rico Board of Pharmacy

Section 3.02 – Powers, Functions and Duties of the Board

Section 3.03 – Witness Summoning and Taking of Oaths

Section 3.04 – Delegation of Powers

Section 3.01.—Puerto Rico Board of Pharmacy.—

The Puerto Rico Board of Pharmacy is hereby created as a government body attached to the Department of Health, responsible for safeguarding the health of the people, with exclusive power to regulate the admission, suspension, or separation from the practice of the profession of pharmacy and the occupation of pharmacy technician.

(a) Composition of the Board

The Board shall be composed of seven (7) members appointed by the Governor of Puerto Rico with the advice and consent of the Senate. The College of Pharmacists of Puerto Rico shall submit to the Governor a list of candidates. The Governor may appoint the members of the Board from among the candidates included in said list or any other person who meets the requirements set forth in this Act.

(b) Term of the Appointments

The members of the Board shall be appointed for a four (4)-year term and shall discharge their office until the expiration of the term their respective appointment, or until their successors are appointed and take office. No person may be appointed as member of the Board for more than two (2) consecutive terms.

(c) Requirements of the Members of the Board

Six (6) members of the Board shall be pharmacists and one (1) shall be a pharmacy technician. All members shall be of recognized moral standing, residents of Puerto Rico and have practiced their profession or occupation for at least five (5) years immediately preceding the date of the appointment. At the time of their appointment, not less than three (3) members of the Board shall be practicing their profession in a Community Pharmacy, one (1) of the Pharmaceutical Industry, and one (1) in an institutional pharmacy. No member of the Board shall own, be a stockholder in or belong to a Board of Trustees or a Board of Directors of a university, college or technical college in which studies leading to a degree in the field of pharmacy or pharmacy technician are offered.

(d) Vacancies

Any vacancy in the Board before the expiration of the member's term, shall be filled in the same manner in which the original appointment was made and the new member shall carry out his/her functions for the term provided in subsection (b) of this Section.

Whenever a vacancy occurs due to the expiration of any of the member's appointment term, the Chairperson of the Board shall notify such event to the Governor and the College of Pharmacists within not less than sixty (60) days before the expiration date of said appointment, in order to expedite the appointment process of the new member. The College of

Pharmacists shall submit a list of candidates to the Governor. The Governor may appoint the members of the Board from among the listed candidates or appoint any other person who meets all the requirements established in the Act.

(e) Removal from Office

The Governor may remove from office any member of the Board for negligence in the performance of his/her duties as member thereof, for negligence in the practice of his/her profession or occupation, for conviction for a misdemeanor or felony involving moral turpitude or for having his/her pharmacist or pharmacy technician license suspended, cancelled, or revoked.

(f) Per Diems

The members of the Board shall not receive salary, fees, compensation or remuneration whatsoever for the performance of his/her functions. However, the members of the Board, including public officials or employees, shall be entitled to a per diem for each day or fraction thereof for each meeting they attend, which per diem shall be equal to the minimum per diems established for the members of the Legislature, except for the Chairperson of the Board, who shall receive a per diem equal to one hundred and thirty three percent (133%) of the per diem received by the other members of the Board. In addition, any traveling expenses incurred in the performance of his/her functions shall be reimbursed, subject to the applicable regulations of the Department of the Treasury.

(g) Meetings and Quorum

The Board shall hold at least six (6) regular meetings every year to address and resolve official matters. It may hold any necessary special meetings for the best performance of its functions, upon previous notice to the members at least twenty-four hours before the meeting. Four (4)

members shall constitute a quorum in a duly-called Board meeting and the agreements shall be reached by the majority vote of its at the time of the vote.

(h) Internal Operations

The Board shall elect a Chairperson and a Vice-Chairperson from among the pharmacists who compose the same. The Vice-Chairperson shall perform the functions of the Chairperson in the event of his/her temporary absences. Both officials shall hold office for a one(1)-year term, counting from the date of their respective election, and may be reelected for not more than two (2) additional consecutive terms.

The Board shall adopt regulations for its internal operations and shall record all its proceedings in the appropriate minute book. Each minute shall be signed by the members who have attended such meeting.

Section 3.02.—Powers, Functions, and Duties of the Board.—

In addition to any other provided by this Act, the Board shall have the following powers, functions, and duties:

(a) Authorize the practice of the profession of pharmacy and pharmacy technician occupation to those candidates who meet all the requirements established by this Act and issue the Pharmacist license or pharmacy technician certificate, as it corresponds, with the signature of all members of the Board.

(b) Deny, suspend, or revoke the any the pharmacist license or pharmacy technician certificate to any person who fails to comply with the provisions of the laws and code of ethics which regulate the practice of the profession of pharmacist or the pharmacy technician occupation and the manufacture, distribution and dispensing of drugs;

(c) Administer the licensure examination to applicants for a pharmacist license or for a pharmacy technician certification at least twice (2x) a year;

(d) Authorize internships, establishing by regulations the criteria and standards applicable to practice centers, preceptors and interns.

(e) Authorize or deny recertification to a pharmacist or pharmacy technician as required, and pursuant to the terms and conditions set forth in Act No. 11 of June 23, 1976, as amended, as well as those of this Act.

(f) Evaluate and acknowledge certificates for specialties within the profession of pharmacy granted to pharmacists authorized by renowned professional agencies and institutions.

(g) Prepare and up date a register of the pharmacist licenses and pharmacy technician certificates issued, including, among others, the following information: (1) full name of the license or certificate holder; (2) date of issue and of each subsequent recertification; (3) home address and place in which he/she practices the profession of pharmacy or the pharmacy technician occupation, as the case may be;

(h) Develop and keep a confidential information system on denied, issued, or revoked licenses and certificates, including the score of the pharmacist and pharmacy technician certification examination, the characteristics of the holders as to their age, sex, last school attended, grade point average at the beginning and the end of their professional or technical studies, and any other characteristics or information deemed necessary and convenient by the Board to keep updated a reliable and appropriate information system;

(i) Establish statistical relations on the data of the information system, maintaining the confidentiality of the personal information of the affected persons;

(j) Approve and promulgate the necessary norms to regulate the practice of the profession of pharmacy and of the pharmacy technician occupation with the purpose of protecting and ensuring the best health, safety and welfare to the people;

(k) Initiate investigations or administrative procedures on their own or by a duly sworn complaint or formal complaint filed before the Secretary of Health, the Secretary of Justice or the College of Pharmacists against a pharmacist, pharmacy technician, pharmacist intern, or pharmacy technician intern who incurs in violation of the provisions of the laws and code of ethics that regulate the profession of pharmacy and the pharmacy technician occupation and the manufacture, distribution and dispensing of drugs, endangering the public health.

(l) Establish consultation and coordination mechanisms that are necessary to perform its functions and to comply with the purposes of this Act, including the contracting, upon previous approval of the Secretary, of essential professional and technical services;

(m) Submit recommendations to competent authorities as to the norms and procedures for the evaluation of educational programs for pharmacists and pharmacy technicians offered in any public or private educational institution in Puerto Rico;

(n) Establish the procedures and mechanisms it deems convenient to achieve the interchange of information with those higher education institutions of Puerto Rico and abroad which have programs, colleges, or schools engaged in the teaching of pharmacy or in the formation and

education of pharmacy technicians, on the latest advances, development, discoveries and studies in the pharmacy field.

(o) Execute agreements or compacts with examining boards or similar entities of other jurisdictions to interchange information on denied, suspended or revoked pharmacist licenses and pharmacy technician certificates.

(p) Enter into reciprocity agreements for the practice of the profession of pharmacy with competent and official bodies or entities of other United States jurisdictions;

(q) Participate together with government agencies, professional organizations and associations in activities directed to promote the improvement of standards of the pharmacy practice for the protection of the public health and welfare;

(r) Keep a detailed thorough register of all higher education institutions of Puerto Rico having accredited pharmacy colleges or programs and of educational institutions accredited or recognized by the pertinent authority offering pharmacy technician program;

(s) Collect any fees established in this Act, which shall be covered into a special account as provided in Section 4.15, issue the corresponding receipt and keeps a complete and thorough accounting on the collected and received sums;

(t) Receive and use funds received from sources other than the State, or from fees, provided (1) said funds have been granted for a specific purpose that the Board is authorized carry it out by this Act to; (2) said funds are used to attain the purpose for which they were granted; (3) keep said funds in a separate account; (4) submit periodical reports to the Secretary on the receipt and expenditure of said funds; and (5) activities in

which said funds are spent shall not interfere nor conflict with the duties and responsibilities of the Board.

(u) Adopt an official seal which shall be affixed on the original of every official document issued by the Board;

(v) Adopt any rules and regulations necessary to enforce this Act pursuant to the provisions of Act No. 170 of August 12, 1988, as amended, known as the “Commonwealth of Puerto Rico Uniform Administrative Procedures Act;”

(w) Submit to the Governor, through the Secretary, an annual report on the works and efforts made during the year corresponding to such report, the same shall include, without it being understood as a limitation: statistical data on licenses, certificates, permits, and recertification issued, denied, and revoked, complaints pending resolution at the time of the report, any income received by the Board and any other information required by the Secretary or that, at the judgment of the Board, is pertinent.

Section 3.03.—Witness Summoning and Taking of Oaths.—

The Board may summon witnesses and compel their appearance before the Board as a whole or before any of its members to which the investigation of an issue or the examination of a document has been entrusted, to testify or to present any book, file, register, record or document of any kind related to a matter within the jurisdiction of the Board. All summons issued by the Board bear its official seal and be signed by the Chairperson thereof.

The Board shall have the power to resort to the Court of First Instance to in aid of its jurisdiction to compel appearance. The Court, upon proof of just cause, may issue an order for the person to appear before the Board, to

testify and present the required documents on said issue. Failure to follow such order shall constitute contempt of court and may be punished as such.

The members of the Board are hereby empowered to take oaths on statements or testimonies related to the issues under the jurisdiction of the Board, thus keeping a separate register for each member of the Board of the statements taken, indicating the date of the sworn statement, complete name and personal circumstances of the person testifying or taking oath and a brief account of the contents of the sworn statement.

Section 3.04.—Delegation of Functions.—

The Board may delegate on one or more Examining Officials any of its investigative and adjudicative powers and functions, including the power to take oaths, summon witnesses and require the furnishing of documentary evidence and of other kind.

CHAPTER IV
REGULATIONS OF THE PHARMACIST
AND THE PHARMACY TECHNICAN

- Section 4.01 – Requirements to Practice the Profession of Pharmacy**
- Section 4.02 – Requirements to Obtain a Pharmacist License**
- Section 4.03 – Application for Pharmacy Licensure**
- Section 4.04 – Pharmacist Licensure Examination**
- Section 4.05 – Reciprocity of the Pharmacist License**
- Section 4.06 – Granting of a Pharmacist License and Recertification**
- Section 4.07 – Certification of Specialization in the Profession of Pharmacy**

- Section 4.08 – Requirements to Practice the Pharmacy Technician Occupation**
- Section 4.09 – Requirements to Obtain a Pharmacy Technician Certificate**
- Section 4.10 – Application for the Pharmacy Technician Certification Examination**
- Section 4.11 – Certification Examination of the Pharmacy Technician**
- Section 4.12 – Reciprocity in the Certification of Pharmacy Technician**
- Section 4.13 – Granting of a Pharmacy Technician Certification and Recertification**
- Section 4.14 – Denial, Suspension, Cancellation or Revocation of a License or a Certification**
- Section 4.15 – Fees**

Section 4.01.—Requirements to Practice the Profession of Pharmacy.—

Only those persons who meet the following requirements shall practice the profession of pharmacy in Puerto Rico:

(a) Hold a pharmacist license obtained pursuant to the provisions of this Act or a pharmacist license in effect obtained pursuant to the provisions of the Act herein repealed;

(b) Have his/her license and recertification registered in the Register of Pharmacists of the Health Professionals Regulations and Certifications Office, as provided by this Act;

(c) Be an active member of the College of Pharmacists of Puerto Rico, pursuant to the provisions of Act No. 243 of May 15, 1938, as amended.

Section 4.02.—Requirements to Obtain a Pharmacist License.—

Any person who wishes to obtain a license to practice the profession of pharmacy in Puerto Rico shall meet the following requirements:

(a) Be of legal age and submit a negative criminal history certificate;

(b) Hold a diploma evidencing that he/she has obtained a degree in said profession from a higher education institution or school of pharmacy in Puerto Rico or abroad, the study program of which is accredited or acknowledged by the Council on Higher Education of Puerto Rico or its successor. Such accreditation or acknowledgment shall be based on the criteria established by said agency in consultation with the Board of Pharmacy and in harmony with the standards of accreditation of the American Council of Pharmaceutical Education. Those persons graduated from schools of pharmacy of foreign countries shall submit a certificate of educational equivalency granted by the National Association of Boards of Pharmacy.

(c) Having satisfactorily completed an internship period of a minimum of one thousand five hundred (1,500) hours under the supervision of a preceptor pharmacist. The Board may increase, by regulations, the number of hours required after having notified the schools of pharmacy of Puerto Rico within at least one (1) year before. The internship may be carried out entirely in one pharmacy or as provided by the Board by regulations, one part in a community or institutional pharmacy, and another part in the pharmaceutical industry or in another area in which the profession

is practiced. In the case the pharmacy intern is a student enrolled in supervised practice courses in an accredited school of pharmacy, the criteria and standards established by the Board through regulations for these cases shall apply.

(d) Having approved the licensure examination required by this Act.

(e) Having paid the license fees established by this Act.

Section 4.03.—Application for the Pharmacy Licensure.—

Any person who wishes to take the licensure examination required by this Act to obtain the pharmacist license, shall submit to the Board the following documents:

(a) An application for the licensure examination on the form provided by the Board to these effects and in the manner and within the term prescribed by regulation;

(b) Evidence accrediting that the applicant meets the requirements established by subsections (a), (b), and (c) of Section 4.02 of this Act;

(c) An official document with photo and signature accrediting the identity of the applicant;

(d) The payment of pharmacist licensure examination fees established by Section 4.15 of this Act.

The applicants who fail the examination and want to repeat the same must submit a new application.

Section 4.04.—Pharmacy Licensure Examinations.—

(a) Purpose of the Licensure Examination

The purpose of the pharmacy licensure examination is to assess the competencies of the applicant to initiate the practice of the profession.

(b) Examinations

The licensure examination for the candidates to a pharmacist license shall be comprised of two (2) examinations: a general examination and another on the legal aspects of the practice of pharmacy. The general examination shall measure the application of knowledge, judgment and skills needed for the practice of pharmacy and the other shall measure the application of knowledge in legal aspects of the practice of the profession.

The Board may employ consultants or agencies engaged in the preparation and evaluation of licensure examinations, but shall hold responsibility on the content of such examinations and on the determination of the minimum passing score which shall be obtained to approve the licensure.

(c) Examinations of the National Association of Boards of Pharmacy

The Board, at the choice of the candidate, may offer the general examination and/or the examination on the legal aspects administered by the National Association of Boards of Pharmacy, in lieu of the corresponding examinations prepared by the Board.

The candidates who choose to take these examinations shall pay the cost thereof, as established by the National Association of Boards of Pharmacy, in addition to the examination application fee established by this Act.

(d) Orientation to Candidates

The Board shall prepare and publish a handbook with the necessary information for the candidate to become acquainted with the standards and procedures that govern the administration of the examinations, types of examinations, methods of evaluation, and the minimum score required for its

approval. This handbook shall be furnished to every person who requests admission for the licensure examination, upon previous submission of a money order or check payable to the Secretary of the Treasury, or credit or debit card, following the standards of the Secretary of the Treasury with regard to the form of payment. The Board shall determine the cost of such handbook taking as a base the costs of its preparation and publishing. The amount to be charged shall not exceed the real cost such expenses represent. The funds thus collected shall be covered into the special account established in Section 4.15 of this Act.

(e) Score of the Licensure Examination

The Board shall establish, by regulations, the minimum passing score that the candidate must obtain to approve the licensure examination and the standards and procedures which shall govern the administration and evaluation of the examination. The right to verify their answers in the examination shall be granted to the candidates, within the next ninety (90) days after the date they receive the results thereof.

The candidate may repeat the examination in which he/she obtained a lower score than the minimum score required up to a maximum of five (5) times. For the purposes of the license issuance, the examinations shall expire six (6) years after their approval.

Section 4.05.—Reciprocity of the Pharmacist License.—

(a) The Board may issue a pharmacist license to any person who holds a valid license issued by the Board of Pharmacy or by other competent entity from any jurisdiction with which the Board has a reciprocity agreement in effect, provided said person meets the following requirements:

1. Be of legal age and present a negative criminal history certificate;

2. Be a graduate from a pharmacy college or school which is recognized or accredited by the highest pertinent accrediting authority in Puerto Rico based on criteria established by said agency in consultation with the Board of Pharmacy;

3. Have not less than one (1) year experience in the practice of the pharmacy profession in the jurisdiction where he/she has obtained his/her pharmacist license;

4. Pass the examination on legal aspects of the practice of pharmacy as stated in Section 4.04 (b) or (c) of this Act;

5. Have not incurred any of the causes established in this Act for denying of a pharmacist license in the jurisdiction where he/she has obtained his/her license or in another in which he/she has practiced the pharmacy profession;

6. Meet all other applicable requirements established in this Act to practice the pharmacy profession in Puerto Rico as provided by the Board by regulations.

(b) Any pharmacist who wishes to obtain a license pursuant to the provisions of this Section shall file with the Board the following documents:

1. An official document with photo and signature which attests to his/her identity;

2. An application for the examination on legal aspects and a reciprocity license application, in the forms provided by the Board to that effect;

3. Evidence attesting that he/she meets the requirements established in subsection (a.1), (a.2), (a.3), and (a.5) of this Section;

4. The original of his/her pharmacist license, together with a certification issued by the competent authority attesting that said

license has not been revoked, temporarily suspended, or otherwise restricted;

5. The payment of the fees for the pharmacist licensure examination application, as established in Section 4.15 of this Act.

(c) In the event the applicant does not pass the examination on legal aspects as required, he/she may take it again by submitting a new examination application together with the corresponding fees.

(d) The limitations and restrictions established in Section 4.04 of this Act on the number of chances to take licensure examinations shall apply to any examination application submitted pursuant to this Section.

Section 4.06.—Granting the Pharmacist License and Recertification.—

(a) Granting the License

The Board shall grant a pharmacist license to any person who meets the requirements established in Sections 4.02 through 4.05 of this Act, as the case may be, after having paid the license fees fixed in Section 4.15(a) of this Act.

The pharmacist license shall have the form, registration, characteristics, information, numbering, series or identification as established by regulations. The Board shall register said license in the Register of Pharmacists of the Health Professionals Regulations and Certifications Office.

The pharmacist license, once it has been issued and registered pursuant to the provisions of this Act, except if suspended, cancelled, or revoked, authorizes the person to whom it is issued to exercise the functions and prerogatives of the pharmacy profession, as established in this Act.

(b) Recertification

Any pharmacist who wishes to continue practicing the pharmacy profession in Puerto Rico shall apply to the Board for his/her recertification every three (3) years, as required by Act No. 11 of June 23, 1976, as amended, and by the regulations adopted thereunder. The recertification application shall be made using the form provided by the Board to that effect and be submitted together with the following documents:

1. Evidence attesting that the applicant has met the continuing education requirement, as required under the aforementioned Act No. 11 and its regulations;
2. A certification from the College of Pharmacists of Puerto Rico, attesting that the applicant is an active member of said entity;
3. The payment of pharmacist recertification fees as provided in Section 4.15 of this Act.

The Board shall issue the recertification not later than thirty (30) days after the date of having submitted the application, and shall order the corresponding registration into the Register of Pharmacists of the Health Professionals Regulations and Certifications Office.

Section 4.07.—Certification for Specialties Under the Pharmacy Profession.—

The Board may grant certification as a specialist in an area of the pharmacy profession to any authorized pharmacist who holds a specialty certificate granted by a recognized professional institution or agency. The Board shall establish through regulations the criteria and procedures for granting a specialty certificate.

No pharmacist may advertise or purport to be a specialist in an area of the pharmacy profession in Puerto Rico if he/she does not hold a specialty certificate issued by the Board.

Section 4.08.—Requirements to Practice the Pharmacy Technician Occupation.—

Only the persons who meet the following requirements shall be able to practice the pharmacy technician occupation in Puerto Rico:

(a) Hold a certificate obtained pursuant to the provisions of this Act or a certificate in effect obtained pursuant to the provisions of the law which is hereby repealed;

(b) Have his/her certificate and recertification registered into the Register of Pharmacy Technicians of the Health Professionals Regulations and Certifications Office.

Section 4.09.—Requirements to Obtain a Pharmacy Technician Certificate.—

Any person who wishes to obtain a pharmacy technician certificate shall meet the following requirements:

(a) Be eighteen (18) years old or older, and submit a negative criminal history certificate;

(b) Have approved the high school general course in a school in Puerto Rico which is recognized by the Department of Education or in a school accredited by the corresponding authority of the place where the same is located;

(c) Have a diploma, a certificate or any other official document attesting that he/she has satisfactorily approved a pharmacy technician course in an educational institution in Puerto Rico which is accredited by the highest corresponding accrediting authority, as the case may be, or in an institution of the United States or the United States Armed Forces which is recognized or accredited by the corresponding Authority in Puerto Rico and

that, to the satisfaction of the Board, meets the minimum requirements of the pharmacy technician course;

(d) Have satisfactorily completed an internship period for a minimum term of one thousand (1,000) hours under the direct supervision of a preceptor pharmacist in a pharmacy. The Board may, by regulation, increase the minimum number of internship hours required after having notified the institutions with academic programs for pharmacy technicians in Puerto Rico, not less than one (1) year in advance of the date on which the change was approved;

(e) Have passed the pharmacy technician certification examination, as required under this Act;

(f) Have paid the fees for the pharmacy technician certification established under this Act.

Section 4.10.—Pharmacy Technician Certification Examination Application.—

Any person who wishes to take the certification examination application required under this Act to obtain a pharmacy technician certificate, shall submit the following documents to the Board:

(a) A certification examination application, on the form provided by the Board and within the term it establishes by regulations;

(b) Evidence attesting that the applicant meets the requirements established in subsections (a), (b), (c), and (d) of Section 4.09 of this Act.

(c) An official document with a photograph and signature attesting to the identity of the applicant;

(d) The payment of the fees for the application to take the pharmacy technician certification examination, as established under Section 4.15 of this Act.

Candidates who do not pass the certification examination and wish to take the examination again, shall submit a new application.

Section 4.11.—Pharmacy Technician Certification Examination.—

(a) Purpose of the Certification

The purpose of the certification is to assess the competencies of the candidate to begin practicing the pharmacy technician occupation.

(b) Examination

The certification examination shall consist of a written exam on the application of the concepts of the following subjects: pharmacy math; pharmacotherapy; and technical, administrative, and legal aspects of the practice of pharmacy.

The Board may offer the candidate the option of taking the examination prepared by the National Pharmacy Technician Certifying Board, in which case, the candidate shall also take the examination on the legal aspects of the pharmacy profession offered by the Board.

The Board, when necessary to assess the competency of such candidates, may substitute or include other subjects in the examination. This change shall take effect two (2) years after the date of its approval and shall be published in a newspaper of general circulation in Puerto Rico and notified to the educational institutions of Puerto Rico with pharmacy technician programs or courses, within sixty (60) days from the date of its approval.

(c) Certification Examination Passing Score

The Board shall prepare and offer the examination to candidates for certification as pharmacy technicians, following the criteria, norms and procedures established by regulations. The Board may use consultants or agencies engaged in preparing and evaluating certification examinations.

The minimum score or grade to be obtained in order to pass the examination shall be fixed by regulation. Candidates shall be guaranteed their right to review their answers in the examination within ninety (90) days from the date of receipt of the examination results.

In the candidate fails to obtain the minimum score, he/she may take the examination again up to a maximum of five (5) times. For the purpose of issuing the certificate, the examination shall expire after six (6) years of its approval.

(d) Examination Orientation

The Board shall prepare and publish a handbook with information to acquaint candidates with the norms and procedures of the licensure, the administration of the examination, the type of examination, the evaluation method and the minimum score required to pass. The handbook shall be given to all candidates applying for the certification examination after they have provided a check or money order payable to the order of the Secretary of the Treasury or a credit or debit card, following the norms established by the Secretary of the Treasury concerning this means of payment, for the amount to be determined by the Board, taking as a base the expenses incurred for its preparation and publication. The amount to be charged may not exceed the actual cost represented by said expenses. These funds shall be covered into the special account provided for in Section 4.15.

Section 4.12.—Pharmacy Technician Certificate Reciprocity.—

The Board shall establish by regulation the norms and procedures for reciprocity concerning pharmacy technician certificates.

Section 4.13.—Granting of Certificate and Recertification as Pharmacy Technician.—

(a) Granting of Certificate

The Board shall grant a pharmacy technician certificate to any person who meets the requirements established in this Act, after he/she has paid the certificate fees fixed therein.

The certificate shall be have the form, registration, characteristics, information, number, serial number or identification established by regulation. The Board shall register said certificate in the Register of Pharmacy Technicians of the Health Professionals Regulation and Certification Office.

The pharmacy technician certificate issued and registered pursuant to the provisions of this Act, except if suspended, cancelled, or revoked, authorizes the person to whom it is issued to discharge the functions set forth in this Act under the direct or immediate supervision of a pharmacist.

(b) Recertification

Any pharmacy technician who wishes to continue practicing as such in Puerto Rico shall apply to the Board his/her recertification every three (3) years, as required by Act No. 11 of June 23, 1976, as amended, and by the regulations adopted thereunder.

The recertification application shall be made on the form provided by the Board to that effect and be submitted together with the following documents:

1. Evidence attesting that the applicant has met the continuing education requirement imposed under the aforementioned Act No. 11 and its regulations.
2. The payment of fees for pharmacy technician recertification, as established in Section 4.15 of this Act.

The Board shall issue the recertification not later than thirty (30) days from the date the application has been submitted and shall order its corresponding registration into the Register of Pharmacy Technicians of the Health Professionals Regulation and Certification Office.

Section 4.14.—Denial, Suspension, Cancellation, or Revocation of License or Certificate.—

(a) Denial of License or Certificate

The Board shall deny a pharmacist license or a pharmacy technician certificate, as the case may be, to any person who:

1. Attempts to obtain said license or certificate through fraud or deceit;
2. Does not meet the requirements established in this Act to obtain such license or certificate;
3. Is found to be mentally unfit by a competent court;
4. Is addicted to controlled substances or alcoholic beverages, provided that once he/she submits evidence that he/she is rehabilitated, the Board may reconsider the denial;
5. Has been convicted during the last ten (10) years of any crime which implies moral turpitude or which alters or is substantially related to the qualifications, functions and duties of the pharmacy profession or the pharmacy technician occupation;
6. His/her conduct or physical condition constitutes a hazard to public health.

(b) Suspension, Cancellation, or Revocation of License or Certificate

The Board may suspend, cancel or revoke the license of a pharmacist or the certificate of a pharmacy technician on the following grounds:

1. He/she has obtained his/her license, certificate or recertification by fraud or deceit;

2. He/she is addicted to controlled substances or alcoholic beverages, provided that the Board may require the pharmacist or pharmacy technician to participate in a treatment or rehabilitation program, after which his/her license may be reinstated after it has been ascertained that he/she has overcome his/her condition;

3. He/she has been convicted for a violation of the Puerto Rico Controlled Substances Act or the Federal Controlled Substances Act, or for any other crime which implies moral turpitude or which affects or is substantially related to the qualifications, functions and duties of the pharmacist profession or the pharmacy technician occupation;

4. He/she is found to be mentally unfit by a competent court;

5. He/she has rendered a false testimony to benefit a candidate for a pharmacist license or a pharmacy technician certificate or in any investigation conducted by the Board or the Secretary of Health;

6. He/she has altered or forged any document or material with the malicious intent to deceive the members of the Board;

7. He/she has allowed, fostered or aided a person to practice as a pharmacist or a pharmacy technician fully aware of the fact that said person does not hold a license or a certificate as such;

8. He/she does not comply with the provisions of the laws and the ethic codes that regulate the practice of the pharmacy

profession and the manufacture, distribution and dispensation of medications;

9. He/she has demonstrated a pattern of crass incompetence in the practice of the profession or the occupation which places the health, safety and welfare of consumers at risk;

10. His/her conduct or physical condition constitutes a hazard to public health.

Section 4.13.—Fees.—

(a) The following fees are hereby established for the items indicated below, provided that the same shall be in effect from the date of approval of this Act until the Board establishes other fees by regulation:

1. Application for pharmacist license examination	\$ 75.00
2. Application for pharmacist technician certificate examination	50.00
3. Internship authorization	10.00
4. Pharmacist license	100.00
5. Pharmacist license by reciprocity	150.00
6. Pharmacy technician certificate	50.00
7. Pharmacist recertification and registration	30.00
8. Pharmacy technician recertification and registration	25.00
9. License or certificate copy	15.00
10. License certification to apply for reciprocity in another jurisdiction	25.00
11. Other certifications related with licenses and certificates	25.00

(b) The fees established herein shall be paid by check or money order payable to the order of the Secretary of the Treasury or by credit or

debit card, following the norms and procedures provided by the Secretary of the Treasury concerning said means of payment.

(c) The amount of the fees for examination applications shall not be refunded to the applicant when he/she fails to show up to the examination or if he/she fails the same.

(d) All funds collected by the Board on account of the fees established in Chapter IV of this Act shall be covered into the Health Fund created under the provisions of Act No. 26 of November 13, 1975, as amended, to be used by the Board of Pharmacy pursuant to regulations approved to that effect.

(e) The Board shall keep in a separate account the funds received by virtue of the provisions of Section 3.02 (s) of this Act.

CHAPTER V

MANUFACTURE, DISTRIBUTION AND DISPENSATION OF MEDICATIONS

Section 5.01 – Medication Register

Section 5.02 – Dispensation of Prescription Medications

Section 5.03 – Interchange of “Bioequivalent Medications”

**Section 5.04 – Medications with Special Dispensation
Requirements**

Section 5.05 – Nonprescription Medications

Section 5.06 – Pharmaceutical Industry

Section 5.07 – Wholesale Distribution

Section 5.08 – Representing Agent

Section 5.09 – Retail Nonprescription Medication Distribution

Section 5.10 – Pharmacy

Section 5.11 – Drug Cabinets

Section 5.12 – Veterinary Facilities

Section 5.13 – Retail Nonprescription Veterinary Medication Distributor

Section 5.14 – Devices

Section 5.15 – License, Certificate and Authorization Effectiveness and Fees

Section 5.16 – Granting, Denial, Suspension, Cancellation or Renewal of Licenses, Certificates and Authorizations

Section 5.01.—Medication Register.—

No person in Puerto Rico may display, offer for sale, distribute, sell, deliver, store, give away or donate, or make any advertisement whatsoever of medications to be used by human beings or other animals unless said medications have been registered under the Department for their marketing, distribution, dispensation and sale in Puerto Rico.

The Secretary shall establish by regulation the procedures for registering medications. Any medications approved by the Food and Drug Administration (FDA) shall be registered upon submittal of a duly completed registration application, together with the payment of the corresponding fees.

Section 5.02.—Dispensation of Prescription Medications.—

(a) All prescription medications shall only be dispensed by a pharmacist in a registered pharmacy authorized by the Secretary to operate as such and pursuant to the provisions of Section 1.03 (i). The pharmacist shall exercise his/her professional judgment as to the accuracy, validity and authenticity of the prescription he/she receives in a manner consistent with the applicable laws and regulations. The pharmacist technician, pharmacist

intern or pharmacist technician intern may intervene in the dispensation of drugs under the direct supervision of the pharmacist as provided by this Act. In the case of prescription medications to be used in animals, these may also be dispensed pursuant to that which is established in Act No. 194 of August 4, 1979, as amended.

(b) Patients shall have the right to freely and voluntarily select the pharmacy by which each prescription is to be dispensed on a case by case basis. Provided, that no physician, medical group, dentist, odontologist, or podiatrist may sell or participate in any profitable business transaction when providing medication samples to any patient.

(c) The prescription shall be the original written order issued and signed by the prescribing professional and shall include the following information, in addition to any other information required under other provisions of this Act and other applicable laws and regulations:

1. date of issue;
2. full name and address of the patient;
3. patient's age;
4. full name, address, telephone number, license number, and signature of the prescribing professional;
5. name of the medication prescribed with dosage, potency and amount;
6. indications for use for the patient.

The pharmacist may complete any information not appearing on the prescription by recording the same on the back of the prescription, after having verified the same with the prescribing professional or the patient, as may correspond.

(d) The labeling of all medications dispensed by prescription shall contain, among other things, the following data: name of the pharmacy with its address and phone number; serial number assigned to the prescription; date of dispensation; name, potency and indications for use of the medication; name and surname of the patient and the prescribing professional; and date of expiration and lot number of the medication.

(e) To expedite the process of filling a prescription, the contents thereof may be transmitted verbally or by electronic means by the patient him/herself or his/her representative or by the prescribing professional to the pharmacy freely selected by the patient or his/her representative, thus guaranteeing the patient's right to freely select his/her pharmaceutical services provider. The pharmacist shall transcribe the prescription transmitted orally upon receipt. Both the prescription transmitted orally and the prescription transmitted by electronic means shall include all the data required under subsection (c) of this Section, and record shall be made of the date and time such transmission was made. The patient or his/her representative shall hand over the original prescription to the pharmacist at the time of receiving the prescribed medication.

(f) The pharmacist may refill a prescription as previously authorized by the prescribing professional in original written form or transmitted orally or by electronic means by the prescribing professional to the pharmacy, provided the same is accessible in its original form or by electronic means. The pharmacist shall record the refill on the back of the original prescription or in the patient's pharmacy record by making written note on the prescription or in the electronic database available.

(g) When handling emergency cases, to be defined as provided by the Secretary by regulation, the contents of a prescription may be transmitted

orally or by electronic means directly by the prescribing professional to the pharmacy selected by the patient. The pharmacist shall transcribe the prescription transmitted orally or by electronic means upon receipt. Both the orally transmitted prescription and the electronically transmitted prescription shall include the data required under subsection (c) of this Section. The pharmacist shall record the date and time the transmission was made and shall dispense a limited amount of the medication which shall not exceed the amount needed for a period of one hundred twenty (120) hours. The prescribing professional who transmitted the contents of the prescription orally or by electronic means shall deliver the prescription to the pharmacy that filled the prescription not later than one hundred twenty (120) hours from the time the same was issued. Provided, that in the case of prescriptions for controlled substances, the term provided for such cases under Act No. 4 of June 23, 1971, as amended, shall apply.

(h) Any electronic equipment used to receive prescriptions or prescription refill orders as allowed under subsections (e), (f), and (g) of this Section shall be kept in a suitable location inside the pharmacy counter in order to prevent the same from being accessed by unauthorized persons and to guarantee the right to privacy of patients.

(i) No prescription shall be filled after six (6) months have elapsed from its date of issue. This shall likewise apply to prescription refills.

(j) When filling a prescription or verifying the filling of a prescription when a pharmacy technician, a pharmacist intern or a pharmacy technician intern has intervened in filling the prescription, the pharmacist must sign the prescription on the front at the bottom right.

(k) Pharmacists may interchange a prescribed drug by a bioequivalent medication following the criteria and procedures established in this Act and the regulations adopted thereunder.

(l) The filling of a prescription shall include the delivering and the person-to-person confidential orientation by the pharmacist to the patient or his/her authorized representative.

(m) The prescription shall be filed in a secure place at the pharmacy counter for a minimum term of two (2) years, from the date of dispensation. The information on the prescription and any notes made thereon as required by this Act or other applicable laws, as well as the patient's pharmacy record, may be kept on electronic files. In the case of controlled substance prescriptions, the provisions of Act No. 4 of June 23, 1971, as amended, known as the Puerto Rico Controlled Substances Act, shall apply.

(n) All prescriptions, as well as patient pharmacy records and the information contained in any of these, shall be considered to be confidential information. This information is privileged and may only be disclosed, regardless if in writing or kept by electronic means: (1) to the patient or another person authorized by the latter; (2) to other health care providers of the patient, when according to the professional judgment of the pharmacist, the disclosure of such information is necessary to protect the health and welfare of the patient; and (3) when so required by government agencies or officials authorized by law to receive such confidential information in the exercise of their investigative, adjudicative or overseeing powers or by court order. In order to guarantee the patient's right to the privacy of his/her protected health information, the pharmacy shall comply with all applicable provisions of the Health Insurance Portability and Accountability Act of 1996, better known as HIPAA.

(o) The Secretary shall provide by regulation the norms, requirements, and procedures necessary to implement the provisions of this Section.

Section 5.03.—Interchange of Bioequivalent Medications.—

(a) Drugs that may be Interchanged

The interchange of a prescribed medication for a bioequivalent medication shall be allowed in Puerto Rico when the therapeutic equivalence of the latter has been recognized by the U. S. Food and Drug Administration (FDA), and the same is codified as such in the Approved Drug Products with Therapeutic Equivalence Evaluations, better known as the Orange Book.

(b) Pharmacist's Authority to Interchange Bioequivalent Medications

The pharmacist may interchange bioequivalent medications in the manner stated below:

1. When a medication is prescribed under a brand name or trademark, it shall be construed that any medication which is bioequivalent to the latter has been prescribed, unless the prescribing professional writes down in his/her own handwriting the phrase "Do Not Interchange." The pharmacist shall advise the patient or his/her authorized representative of the possibility of interchanging the prescribed medication; provided, that in all cases the patient or his/her representative must be over the age of eighteen (18). If the patient or his/her representative agrees to the interchange, the pharmacist shall choose that bioequivalent medication which meets each and every one of the following conditions:

- a. The same is included in the Orange Book under a codification starting with the letter "A";

b. The same costs less than the prescribed medication. In the event the prescribed medication or another at a lesser price is not available, an equally priced medication may be dispensed, if the patient or his/her representative agrees;

c. The patient or his/her representative has given his/her consent to interchanging each medication in particular by signing the prescription on the back.

2. If the patient requests to interchange the prescribed brand name medication despite the fact that the prescribing professional has written down in his/her own handwriting the phrase "Do Not Interchange," the pharmacist shall obtain the authorization of the prescribing professional before interchanging the medication and record in the patient's pharmacy record or on the back of the prescription that date and time in which he/she obtained such an authorization.

3. When a medication is prescribed under its generic name, the pharmacist shall choose the generic medication or the brand name product available which costs the less.

4. When interchanging the medication, the pharmacist shall record in the patient's pharmacy record or on the back of the prescription the date on which the medication is interchanged and he/she shall sign the prescription. The pharmacist shall also record on the back of the prescription the brand name or trademark of the medication thus dispensed. Should the medication have no brand name or trademark, he/she shall record the generic name and the name of the manufacturer or distributor that appears on the medication's label.

5. The pharmacist shall label the product thus dispensed with the brand name or trademark in the event he/she has dispensed a brand name product, or with the generic name and the name of the manufacturer, in the event he/she has dispensed a generic product.

6. When interchanging a prescribed brand name medication for a bioequivalent medication pursuant to the provisions set forth in this Section, the pharmacist shall not incur any liability other than that which he/she may incur if he/she dispenses the prescribed brand name medication.

(c) List of Most Frequently Used Bioequivalent Medications

Pharmacies shall post in a visible place accessible to consumers, a list of at least twenty-five (25) most frequently used medications with their bioequivalent medications and their prices.

(d) In any pharmacy coverage under a health services plan, all the provisions of this Act concerning the interchange for bioequivalent medications shall apply.

Section 5.04.—Medications with Special Dispensation Requirements.—

(a) Controlled Substances

Pharmacists shall dispense controlled substances defined in Act No. 4 of June 23, 1971, as amended, known as the “Puerto Rico Controlled Substances Act” and the “Federal Controlled Substances Act,” following the criteria and procedures established in said acts and their regulations.

(b) Radioactive Medications

For the dispensation of radioactive medications or radiopharmaceuticals, pharmacists must comply with all Commonwealth and Federal requirements concerning the management of radioactive

substances. All radiopharmacies shall obtain from the Secretary a special authorization to dispense said medications and meet the criteria and requirements to be established by regulation.

(c) Parenteral Medications

For the composition and dispensation of sterile parenteral medications or any other medications requiring special aseptic techniques, pharmacies shall request and obtain from the Secretary a special authorization for dispensing such medications and meet the requirements to be established by regulation.

(d) Biological Products

For the dispensation or dispatching of biological products, a license shall be requested and obtained from the Secretary as provided by the Regulations of the Department of Health for the Conservation and Registration of Biological Products. Biological products shall be kept refrigerated at a temperature not higher than 12.5 degrees centigrade or 55 degrees Fahrenheit, or according to manufacturer's specifications.

Section 5.05.—Nonprescription Medications.—

(a) Nonprescription medications, with the exception of those indicated further, may be acquired in pharmacies and other establishments duly authorized by and registered at the Department.

(b) The following nonprescription medications may only be acquired at pharmacies:

1. Nonprescription medications containing controlled substances as defined in Act No. 4 of June 23, 1971, as amended, known as the Puerto Rico Controlled Substances Act;

2. Injectable medications;

3. Medications requiring refrigeration for their storage and conservation;

4. Other medications as determined by the Department by regulation.

(c) The Department may exercise the rulemaking authority conferred thereto under the preceding subsection (b)(5) only when it determines, based on studies conducted pursuant to generally accepted scientific criteria, that there is a substantial risk of serious adverse effects on health which are directly attributable to the consumption, abuse or inadequate administration of the medication.

(d) Nonprescription medications shall be kept in their original package with the manufacturer's labeling and kept in an appropriate environment and at an appropriate temperature so that their quality, purity and potency do not deteriorate or are not diminished in any way.

Section 5.06.—Pharmaceutical Industry.—

(a) Any industry engaged in the manufacture of medications shall hold a license from the Secretary which authorizes it to manufacture, market and distribute the same in Puerto Rico. It shall also meet the following requirements:

1. It shall have one (1) or more pharmacists who shall participate in the multidisciplinary team which ensures compliance with the provisions of laws and regulations of the Department of Health and other government agencies concerning the manufacture, packaging and distribution of medications in Puerto Rico. The industry shall give the Department of the Health notice of the identification of the head pharmacist regardless of the number of pharmacists working on its interdisciplinary team.

2. It shall pay the fees established by this Act for the operation of a pharmaceutical industry.

Section 5.07.—Wholesale Distribution.—

(a) All wholesaler drugstores, wholesale prescription medication distributors, wholesale nonprescription medication distributors, and wholesale veterinary medication distributors shall apply to and obtain from the Secretary a license authorizing them to conduct their corresponding activity in Puerto Rico.

(b) Wholesale prescription medication distributors and wholesaler drugstores shall have the professional services of at least one (1) pharmacist to oversee controls in the distribution of medications. Oversight shall be understood to be the intervention of the pharmacist in the development, revision, approval, and maintenance of standard operating procedures in connection with storage and distribution of medications as determined by the Secretary by regulation. One of the pharmacists shall be the head pharmacist.

(c) They shall meet the requirements to be established by regulation and pay the corresponding fees. Likewise, they shall have in effect all permits, licenses and authorizations required under any other law in relation to the use of structures, facilities or premises of the establishment in which the activity for which a license is applied for is conducted and those required by any other laws to carry out said activity.

(d) All wholesaler drugstores and wholesale prescription medication distributors, as well as their officials, agents, representatives and employees shall meet prescription medication storage, management, and distribution register keeping requirements as provided under the Federal

Law known as the Prescription Drug Marketing Act of 1987 and the regulations promulgated under this Act.

(e) Wholesaler drugstores and distributors who distribute medications with special dispensation requirements shall meet Commonwealth and Federal requirements concerning their management.

(f) Wholesaler drugstores, pharmaceutical industries and wholesale medication distributors shall distribute medications only to those establishments that are duly authorized by and registered with the Secretary to acquire, sell, administer or dispense said medications.

Section 5.08.—Representing Agent.—

Any person representing a manufacturer or drug distributor who is not engaged in the storage or distribution of these in Puerto Rico, shall apply to and obtain from the Secretary a license that accredits him/her as a representing agent of said manufacturer or distributor. He/she shall be the person authorized to and responsible for requesting and obtaining the register of the medications the manufacturer or distributor markets and distributes in Puerto Rico.

Section 5.09.—Retail Nonprescription Medication Distributor.—

Any retail nonprescription medication distributor shall apply for and obtain a license authorizing him/her to sell nonprescription drugs as provided for in this Act and its regulations. Together with the application for the register certificate, a listing of the nonprescription medications he/she distributes shall be included.

Said medications shall be kept and sold in their original packages, duly labeled by the manufacturer, and shall be kept in an environment and at

a temperature which are appropriate for preserving their quality, purity and potency, pursuant to the manufacturer's specifications.

Section 5.10.—Pharmacy.—

(a) All pharmacies shall apply to and obtain from the Secretary a license authorizing them to operate as such, including the acquisition, sale or dispensation of medications or devices, pursuant to the provisions of this Act. This license shall allow them to participate in any modality of health services rendered in Puerto Rico.

(b) To obtain a pharmacy license, a pharmacy shall:

1. Comply with the norms and procedures as the Secretary determines by regulation to be necessary for the protection of the public health, safety and welfare, which shall include, without it being construed as a limitation, the following:

a. Safety measures for medication management and storage;

b. Minimal equipment and reference books or electronic reference materials that it should have in order to render pharmaceutical services;

c. Procedures for the transfer or disposal of medications, prescriptions, patient pharmacy records and other documents at the time the pharmacy is under new management or closes its operations;

d. It shall have the services of at least one (1) pharmacist while open to the public and designate a head pharmacist, regardless of whether he/she is the only pharmacist working in the pharmacy, who shall be in charge of and responsible for the pharmacy counter;

e. It shall have the permits required for the use of structures or buildings and other indispensable public services, as well as any municipal license, license, permit or authorization required under other laws for the operation of a pharmacy establishment or for the sale of certain products;

f. It shall reserve and keep a physical space for the dispensation of prescription drugs, to be known as the pharmacy counter. The pharmacy counter area shall be designed, built and organized in such a manner so as to allow for patients to receive confidential orientation and the closing thereof in the event the pharmacist is absent. The Secretary shall determine the minimum physical facility requirements that such an area must meet. The pharmacy counter area shall be restricted to the personnel authorized by law to dispense prescription medications, without limiting the pharmacy owner's or administrator's entrance for limited periods of time to carry out necessary administrative functions.

(c) All pharmacies shall be serviced whenever it is open to the public by the pharmacists and pharmacy technicians as necessary to provide safe and adequate pharmacy services. The pharmacist may be absent only in case of an emergency. During said absence, a sign shall be posted so that it is visible, so as to inform the public of said absence. For the duration of said absence, no prescription medications shall be dispensed and the pharmacy counter shall be closed to the public.

(d) A pharmacist may supervise in terms of the dispensation of medications, during the same shift, not more than five (5) pharmacy technicians, or one (1) pharmacy intern or pharmacy technician intern and

four (4) pharmacy technicians, for a maximum of five (5) persons to be under his/her supervision. Under the pharmacist's direct supervision, pharmacy interns may discharge any of the pharmacist's functions. Pharmacy technician interns may discharge technical and administrative functions which do not require a pharmacist's professional judgment, requiring the direct supervision of the latter to discharge functions relative to the dispensation of prescriptions as allowed for pharmacy technicians under Section 2.04 of this Act. Direct supervision shall be understood to be the physical presence of the pharmacist at the pharmacy counter area or the immediate workspace, and the personal review of the task completed. In the event the intern is a student enrolled in supervised practice courses at an accredited school of pharmacy, the criteria and standards established by the Board by regulation for those cases, shall apply. Pharmacy technicians, or pharmacy technician interns or pharmacy interns who perform tasks not relative to the dispensation of medications shall not count for the four person maximum to be under the pharmacist's supervision.

(e) Pharmacy counter personnel shall be duly identified so that the public may easily distinguish the pharmacist, the pharmacy technician, the pharmacy intern, and the pharmacy technician intern from one another.

(f) As of the date of effectiveness of this Act, no physician, medical group, medical corporation, medical partnership, pharmacy benefits administrator, or health insurance company may refer or direct patients to pharmacies in which any of the above has a financial interest. Likewise, no pharmacy may establish a contractual relation or a negotiation which promotes or allows this practice.

(g) Institutional pharmacies shall meet the requirements established in Act No. 101 of June 26, 1965, as amended, and the regulations adopted thereunder and comply with the applicable provisions of this Act.

(h) No pharmacy may falsely advertise the offering of a pharmaceutical service defined in this Act.

Section 5.11.—Drug Cabinets.—

(a) Any person who keeps a drug cabinet shall apply to and obtain from the Secretary, one of the following licenses:

1. Institutional drug cabinet license – for all drug cabinets located in homes for the elderly, resting homes, dispensaries in factories, at-home health services institutions, penal institutions or similar establishments, whereby medications may be acquired and kept, to be administered solely and exclusively to patients at said institutions, or in the case of at-home health services institutions, to be administered to the patient at home, of which the dispatch or delivery for further use by patients is hereby prohibited.

2. Medical office drug cabinet license – for all drug cabinets located in physicians', dentists' or podiatrists' offices, whereby medications may be acquired and kept, to be administered solely and exclusively to patients at said office, as may be necessary in the normal course of the professional practice for the prevention, diagnosis, treatment, relief or management of the patient's condition, of which the dispatch or delivery for further use by patients is hereby prohibited, except for medical samples in their original package and with the original labeling, as identified by the manufacturer.

3. Ambulance drug cabinet license – for all drug cabinets located in Category III ambulance stations, whereby medications may

be acquired and kept as necessary, to be administered solely and exclusively to patients as immediate treatment during an emergency, by physician's orders, or by following the established medical treatment protocols.

4. Educational institution drug cabinet license – for all drug cabinets located in higher education institutions, whereby medications may be acquired and kept as necessary to be used solely and exclusively in teaching or research.

(b) Together with the application for a drug cabinet license, the following documents shall be submitted, as applicable:

1. a copy of the medical professional's license, a professional registration certificate, and a specialty certificate issued by the corresponding examining board;

2. a copy of the higher education institution accreditation documents;

3. a list of the medications to be kept in the drug cabinet and the amounts necessary in agreement with the normal course of the professional practice, the physician's specialty or the kind of institution, being it understood that these medications are to be acquired pursuant to that which is provided in this Act.

(c) No prescriptions shall be filled and no medications shall be repackaged at the drug cabinets. Medications are to be kept in their original packages with labeling either by the manufacturer or by the pharmacy which dispensed the same as required by law.

Section 5.12.—Veterinary Facility.—

(a) For the operation of any veterinary facility, a license to be known as the "Veterinary Facility License," shall be obtained from the

Secretary. This license authorizes the holder to acquire and keep the medications necessary for veterinarians with their base in said facility to render professional services as authorized under Act No. 194 of August 4, 1979, as amended.

(b) The veterinary facility shall meet requirements such as occupancy permits, municipal license, and any other set forth by the applicable laws and regulations.

(c) The veterinary facility shall be under the charge of a veterinarian, who shall be responsible for ensuring the strict compliance with the measures needed for the adequate preservation, administration and dispatch of medications and devices used at said facility.

Section 5.13.—Retail Veterinary Medication Distributor.—

(a) Any person engaged in the retail sale or distribution of veterinary medications which do not require a prescription shall apply to and obtain from the Secretary of Health a license as retail veterinary nonprescription medication distributor. Provided, that the Secretary of Health, by regulation and in consultation with the Secretary of Agriculture, shall establish the norms, requirements, controls and procedures that shall govern the consideration of an application that any natural or juridical person (conducting business as agricultural supply stores, transporters, for example) may submit in order to obtain a veterinary prescription medication distributor. This license authorizes the holder to sell veterinary prescription medications only when a veterinarian's order has been received. None of the provisions herein shall authorize said person to sell or distribute veterinary products classified as "controlled substances" under the provisions of Act No. 4 of June 23, 1971, as amended, known as the "Puerto Rico Controlled Substances Act." The College of Pharmacists of Puerto Rico, the College of

Veterinarians of Puerto Rico, and the Office of Drug Control of Puerto Rico may investigate any complaint and ensure strict compliance with the laws in effect relative to the sale of veterinary prescription medications in Puerto Rico. The Department of Health shall establish, by regulation, an adequate mechanism for the management and processing of said veterinarian's orders, ensuring that the integrity and the safety of the human food chain are not compromised.

The Secretary shall adopt, by regulation, the requirements for obtaining licenses, as well as the norms, controls and procedures for the retail distribution of veterinary nonprescription medications.

Provided, that any person engaged in the commercial dealing of veterinary medications in Puerto Rico may, at the time of approval of this Act, continue engaged therein for a maximum term of two (2) years from the date of approval of this Act. Once said term has elapsed, he/she shall cease said practice, except in the event he/she is granted the corresponding license under the terms of this Act.

Section 5.14.—Devices.—

The Secretary shall adopt, by regulation, the norms, controls and procedures for the manufacture, distribution, sale, and dispensation of devices.

Section 5.15.—License, Certificate and Authorization Fees and Effectiveness.—

(a) The licenses required under this Chapter shall be in effect for two (2) years from the date of issue and shall be renewed at staggered intervals, after having met the requirements and complied with the procedures to be established by regulation, and after having paid the corresponding fees.

(b) All license renewal applications shall be submitted not later than forty-five (45) days in advance of the date of expiration of the license.

(c) Any person who operates more than one establishment defined in this Act shall apply for and obtain a separate license for each establishment.

(d) Licenses shall be nontransferable.

(e) The license shall be issued under the name of the owner or under the trade name applying for the same and it shall only apply to the establishment at the location stated on the license's front. The license shall also specify the kind of establishment for which the same was granted, as defined in this Act.

(f) The licenses, certificates and authorizations listed below shall be payable at the following fees, which shall be in effect from the date of approval of this Act, until the Secretary establishes other fees by regulation:

1. Medication registration certificate
(each medication) \$ 25.00
2. Pharmaceutical industry license \$ 500.00
3. Wholesale medication distributor license \$ 350.00
4. Wholesaler drugstore license \$ 350.00
5. Representing agent license \$ 200.00
6. Wholesale nonprescription medication
distributor license \$ 100.00
7. Retail nonprescription medication
distributor license \$ 50.00
8. Wholesale veterinary nonprescription medication
distributor license \$ 100.00
9. Wholesale veterinary prescription medication

	distributor license	\$ 100.00
10.	Retail veterinary nonprescription medication distributor license	\$ 75.00
11.	Veterinary facility license	\$ 100.00
12.	Pharmacy license	\$ 100.00
13.	Authorization to distribute and dispense radioactive medications, biological products, or sterile parenteral medications	\$ 25.00
14.	Drug cabinet license	\$ 50.00
15.	License to distribute and dispense biological products	\$ 75.00

(g) License fees shall be paid by money order or check payable to the order of the Secretary of the Treasury or by credit or debit card, following the norms and procedures set forth by the Secretary of the Treasury concerning this means of payment.

(h) The revenues collected from such fees shall be deposited into the Health Fund created under the provisions of Section 11-A of Act No. 26 of November 13, 1975, as amended, to be used exclusively by the Pharmacy Division in overseeing compliance with the provisions of Chapter V of this Act.

Section 5.16.—Granting, Denial, Suspension, Cancellation or Revocation of Licenses, Certificates or Authorizations.—

(a) The Secretary is hereby conferred the exclusive power to grant, deny, suspend, cancel or revoke any of the licenses, certificates or authorizations required under Chapter V of this Act.

(b) The Secretary may suspend, cancel or revoke a license, a certificate or an authorization of any establishment engaged in the

manufacture, distribution, dispensation and sale of medications or veterinary medications or of any drug cabinet when it is determined that:

1. It does not meet the requirements and conditions provided for in this Act and its regulations or in any other law of Puerto Rico or the United States which applies in terms of the management, control, preservation, distribution and dispensation of medications, devices and veterinary products;

2. It is guilty of a violation of any law that applies in terms of the manufacture, distribution and dispensation of medications in Puerto Rico;

3. It is operating without the presence and supervision of a pharmacist in cases which so require;

4. It dispenses prescription medications without the direct or immediate supervision of a pharmacist;

5. It refuses repeatedly and without justification to take certain measures or to correct any deficiency observed by inspector pharmacists.

(c) The Secretary shall direct the closedown of establishments who have had a license, certificate or authorization suspended, cancelled or revoked, and of those operating without a license, certificate or authorization as required by this Act.

(d) Any procedure to grant, deny, suspend, cancel or revoke licenses, certificates or authorizations shall be governed by the provisions on adjudicative procedures established in Act No. 170 of August 12, 1988, as amended, better known as the Uniform Adjudicative Procedures Act.

CHAPTER VI

ADMINISTRATIVE PROVISIONS AND PENALTIES

Section 6.01 – Investigative and Adjudicative Procedures of the Board

Section 6.02 – Powers of the Secretary

Section 6.03 – Medication and Pharmacy Division

Section 6.04 – Investigative and Adjudicative Procedures by the Secretary

Section 6.05 – Cease and Desist Orders

Section 6.06 – Conducts Which Constitute a Crime

Section 6.07 – Administrative Fines

Section 6.01.—Investigative and Adjudicative Procedures of the Board.—

(a) The Board, by its own initiative and when given grounds, or by complaint duly sworn to by any person with personal knowledge of the facts, or by formal complaint by the Secretary of Health, the Secretary of Justice or the College of Pharmacists of Puerto Rico may initiate any investigation or administrative procedure against a pharmacist or a pharmacy technician for a violation of the provisions of this Act or the regulations adopted thereunder. Likewise, it may request the pertinent authorities to investigate any person who purports to be, advertises as or misrepresents him/herself as a pharmacist or a pharmacy technician, and to prosecute said person if the investigation shows that he/she does not hold a license or a certificate to practice as such.

(b) All investigative and adjudicative procedures arising before the Board shall be governed by the provisions and procedures established in Act No. 170 of August 12, 1988, as amended, known as the “Uniform Administrative Procedures Act of the Commonwealth of Puerto Rico.”

(c) The Board may appoint an examining officer to preside administrative hearings and render a report that includes findings of fact and conclusions of law, as well as recommendations for remedies, pursuant to the evidence presented. The Board may adopt said recommendations or reach its own determination based on the full record of the case.

Section 6.02.—Powers of the Secretary.—

(a) The Secretary of Health shall be responsible for enforcing and overseeing compliance with the provisions of this Act. For that effect, he/she shall have the authority to investigate, inspect, summon witnesses, and approve and adopt rules and regulations as necessary in order to render the purposes of this Act practicable.

(b) The Secretary may appoint examining officers to manage the administrative hearings that are to be held pursuant to this Act, and who shall render their reports and recommendations to the Secretary.

Section 6.03.—Medication and Pharmacy Division.—

(a) The Secretary may delegate the function of overseeing compliance with the provisions of Chapter V of this Act, as well as any other related functions, to the Medication and Pharmacy Division, attached to the Office of the Deputy Secretary for Health Facility Regulation and Accreditation.

(b) The Secretary shall appoint a pharmacist with not less than five (5) years professional experience to direct the overseeing functions of the Medication and Pharmacy Division and shall have an adequate number of inspector pharmacists to perform, among others, the following functions:

1. To examine records, documents, inventories, property, physical facilities, premises, transactions, business or any other

materials or activities relative to the manufacture, distribution, and dispensation of medications subject to the provisions of this Act;

2. To recall or seize any unregistered medication pursuant to this Act, or any medication not fit for consumption;

3. To compile the evidence necessary for the prosecution of violators of this Act and the regulations thereunder, in order for these to be prosecuted at the corresponding administrative or judicial forum.

4. To summon witnesses, take oaths, and certify declarations or other documents.

(c) Any document whose examination is pertinent under the provisions of this Act and which is relative to the manufacture, importation, distribution, purchase, dispensation, sale or vending of medications in Puerto Rico, shall be available for inspection by the Secretary. Likewise, any person holding a license, certificate or authorization under this Act, shall facilitate any inspection as required by the Secretary. The fact that the owner or main manager is not present at the establishment shall not be cause or justification to prevent said inspection from being conducted, but the Secretary shall establish by regulation a reasonable maximum term within which any document required during the inspection which was not available at the time, is to be made available for examination. In those cases in which validly obtained documents are not to be used pursuant to that which is provided in this Act, these shall be returned to their owner or legal custodian from whom they were obtained. Documents obtained under this Act shall be classified as confidential, unless their use is allowed by law.

(d) The Medication and Pharmacy Division shall notify the Board of Pharmacy of those violations of this Act and its regulations incurred by

pharmacists and pharmacy technicians. Likewise, it shall notify the College of Pharmacists of Puerto Rico of the violations incurred by pharmacists.

Section 6.04.—Investigative and Adjudicative Procedures by the Secretary.—

Any investigative and adjudicative procedure by the Secretary that arises under the provisions of this Act, as well as the imposition and amount of administrative fines imposed for the violation thereof and the judicial review of final decisions made by the Secretary shall be governed by that which is established in Act No. 170 of August 12, 1988, as amended, known as the “Uniform Administrative Procedures Act of the Commonwealth of Puerto Rico.”

Section 6.05.—Cease and Desist Orders.—

The Board of Pharmacy and the Secretary of Health may issue cease and desist orders on conducts which violate the provisions of this Act and may resort to the aid to the Court of First Instance so that the latter orders compliance therewith.

Section 6.06.—Conducts Which Constitute a Crime.—

(a) Guilty of a misdemeanor, and upon conviction punished by imprisonment for a term not greater than six (6) months or a fine not to exceed five thousand (5,000) dollars, or both penalties, in the discretion of the Court, shall be any person who knowingly and intentionally:

1. Practices, misrepresents him/herself or advertises as a pharmacist or
2. As a pharmacy technician, without holding a license or a certificate issued by the Board of Pharmacy of Puerto Rico.

3. Employs, aids or induces a person who does not hold a license or a certificate from the Board to practice as a pharmacist or a pharmacy technician;

4. Dispenses, sells or delivers medications at an establishment that does not hold the corresponding license, certificate or authorization.

5. Dispenses, dispatches or delivers prescription medications without being a pharmacist, unless a pharmacy technician, a pharmacy intern, or a pharmacy technician intern, and participates in such a function under the direct and immediate supervision of the pharmacist.

6. Dispenses a prescription issued by a prescribing professional who is not a physician, a dentist, a podiatrist or a veterinarian authorized to practice in Puerto Rico and in the United States of America.

7. Being a prescribing professional authorized under this Act, delivers to the patient or his/her representative any medication, except for medical samples in their original packaging and with their original labeling, as identified by their manufacturer.

8. Being a physician, a medical group, a medical corporation or a medical partnership, a pharmacy benefits administrator, or a health insurance company, refers or directs patients to a pharmacy in which any of the above has a financial interest; or that, being a pharmacy, establishes a contractual relationship or negotiation which promotes or allows said practice.

9. Establishes, directs, administers or operates a pharmaceutical industry, a drug cabinet, a pharmacy, a wholesaler

drugstore or any other establishment engaged in the wholesale or retail distribution, dispensation, vending, or sale of medications without holding a license, a certificate or an authorization as required under this Act.

10. Purports to be or misrepresents him/herself, advertises or acts as a representing agent without holding a license as required under this Act.

11. Sells medications to establishments not holding the corresponding license, certificate or authorization under this Act to acquire, sell, administer or dispense the same.

12. Sells, delivers, changes or gives away prescription medication without there being the corresponding prescription issued by a physician, an odontologist, a podiatrist or a veterinarian authorized to practice in Puerto Rico.

13. Displays a sign outside or inside an establishment, advertises in newspapers, on the radio or on television, on fliers or by any other means of promotion or otherwise advertises said establishment with a name that includes the [Spanish] words "*farmacia*," "*droguería*," "*botica*," "*apotecario*," or the English words "drug," "pharmacy," "drugstore," or a combination thereof, or any related word or phrase in any language; or displays any symbol, insignia or emblem traditionally used to identify pharmacies which tends to indicate or insinuate to the public that the establishment is a pharmacy or wholesaler drugstore; or advertises the sale of prescription medications or the rendering of any pharmaceutical service, unless the establishment holds a license to operate as a pharmacy or wholesaler drugstore.

14. Deviates from that which is provided in this Act on the interchange of bioequivalent medications when interchanging medications.

15. If a health services insurance plan, includes in its pharmacy coverage any provisions which are contrary to those established in Section 5.03 of this Act.

(b) Guilty of a felony, and upon conviction punished by imprisonment for one year, shall be any person who:

1. Through the use of force or intimidation, obstructs or impedes inspector pharmacists from discharging their functions concerning the inspection and examination of establishments and activities subject to license, certificate, and special authorization requirements established in this Act.

(c) In cases of recidivism, the person thus convicted shall be further punished by the suspension of his/her professional license for a period not greater than sixty days. Provided, that any natural or juridical person whose financial or other interest are impaired by the practices that are prohibited under this Act shall stand legitimized to bring any action before any forum with jurisdiction to settle controversies arising under this Act. The term "juridical person" shall include associations, partnerships or corporations representing themselves or their components, members or collective membership.

Section 6.07.—Administrative Fines.—

(a) The Board and the Secretary may impose administrative fines for up to a maximum of five thousand (5,000) dollars pursuant to that which is provided in Act No. 170 of August 12, 1988, as amended, on any person who incurs a violation of this Act or of the provisions of the regulations

adopted thereunder; being it understood, that each day the infraction or noncompliance subsists shall be considered to be a separate violation.

(b) Refusal of the offender to pay the administrative fine shall be sufficient grounds for the Board or the Secretary to adopt any other remedy granted under this Act to punish the violation and to suspend any license, certificate, or special authorization obtained under its provisions.

(c) Revenues collected on account of administrative fines shall be covered into the Health Fund created under the provisions of Section 11-A of Act No. 26 of November 13, 1975, as amended, to be exclusively used by the Board of Pharmacy and the Medication and Pharmacy Division, as may correspond.

CHAPTER VII
TRANSITORY PROVISIONS, SEVERABILITY,
AND EFFECTIVENESS

Section 7.01 – Members in Office of the Board of Pharmacy

Section 7.02 – Pharmacy Assistant Apprentice Certificate

Section 7.03 – Compacts, Contracts and Regulations in Effect

**Section 7.04 – Proceedings Initiated Before the Approval of
this Act**

Section 7.05 – Repeal and Amendments

Section 7.06 – Severability

Section 7.07 – Effectiveness

Section 7.01.—Members in Office of the Board of Pharmacy.—

Upon the approval of this Act, members in office of the Board of Pharmacy shall continue to hold office until the expiration date of their respective appointments or until their successors are appointed and take

office. The Governor, with the advice and consent of the Senate of Puerto Rico, shall appoint two (2) additional members to raise the total number of members to seven (7), and they shall hold office for a term of four (4) years, as provided in this Act.

Section 7.02.—Pharmacy Assistant Apprentice Certificate.—

The Board shall ratify, within a term of six (6) months from the date of effectiveness of this Act, all pharmacy assistant apprentice certificates issued under Act No. 282 of May 15, 1945, as amended, for which the holder thereof shall have previously submitted the documents required by the Board by regulation. Together with the submission of documents, holders shall include a check or money order payable to the order of the Secretary of the Treasury or a credit or debit card, following the norms of the Secretary of the Treasury concerning these means of payment, for the amount of ten (10) dollars.

As of the date said certificate has been ratified, the pharmacy assistant apprentice shall have a maximum term of three (3) years to obtain a pharmacy technician certificate, complying with the requirements of said Act. Once the term granted by the Board has lapsed, he/she shall comply with the requirements provided for in this Act to obtain a pharmacy technician certificate.

Section 7.03.—Compacts, Contracts and Regulations in Effect.—

(a) None of the provisions of this Act shall be construed to modify, alter or invalidate any license, certificate, authorization, permit, agreement, compact, claim or contract executed under the provisions of Act No. 282 of May 15, 1945, as amended, or the regulations thereunder. All regulations promulgated under said Act shall continue to be in full force and effect until amended or repealed, provided they are not in contravention of this Act.

(b) The regulations needed to render the purposes of this Act practicable shall be promulgated by the Board and by the Secretary within a term not greater than six (6) months from the date of approval of this Act.

Section 7.04.—Proceedings Initiated Before the Approval of this Act.—

All applications for licensure/certification examinations; pharmacist licenses; pharmacy technician certificates; internship authorizations; establishment licenses to manufacture, distribute or dispense medications; and permits to act as a sales agent; and all proceedings, action or claim pending before the Board of Pharmacy, before the Secretary or before the General Court of Justice on the date of approval of this Act, shall continue to be processed pursuant to the provisions of Act No. 282 of May 15, 1945, as amended, and the regulations in effect, until a final decision is made concerning the same.

Section 7.05.—Repeal and Amendments.—

(a) Act No. 282 of May 15, 1945, as amended, is hereby repealed in its entirety.

(b) Subsections (e), (f), (h), (I i), and (l) are hereby repealed, and the remaining subsections redesignated, respectively, in Section 3 of Act No. 11 of June 23, 1976, as amended.

(c) Subsection (10) is hereby repealed and the remaining subsections renumbered, respectively, in Section 6 of Act No. 11 of June 23, 1976, as amended.

(d) Sections 21, 22, 23, 24, 25, 27, 28, and 29 of Act No. 11 of June 23, 1976, as amended, are hereby repealed.

(e) Section 35 of Act No. 11 of June 23, 1976, as amended, is hereby amended to read as follows:

“Section 35.—Penalties.—

(b) Any person who, for the purpose of obtaining payment for services rendered, presents false information or documents to the Administration, to the Department of Health or to the Council, or who assists other persons in achieving such purposes, shall be guilty of a felony and upon conviction shall be punished by a fine of not less than five hundred (500) dollars nor more than one thousand (1,000) dollars, or by imprisonment for a term of not less than six (6) months nor more than one (1) year, or both penalties in the discretion of the Court.

(b) Any person who, after having been duly summoned by the Administration, the Department or the Council, or any of the bodies created hereby, refuses without good cause to furnish information, data, documents or reports needed to fulfill the purposes of this chapter, or who furnishes false information, data, documents or reports, shall be guilty of a misdemeanor and upon conviction shall be punished by a maximum fine of five hundred (500) dollars, or imprisonment for a maximum term of six (6) months, or both penalties in the discretion of the Court.

(c) Any person who willfully and knowingly violates any of the provisions of Sections 9 through 20 of this Act or the regulations promulgated thereunder, shall be guilty of a misdemeanor, and upon conviction shall be punished by a fine not to exceed five hundred (500) dollars, or imprisonment for a maximum term of six (6) months, or both penalties in the discretion of the Court.

(d) Any person who willfully violates any other provision of this Act shall be guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than one hundred (100) dollars nor more than five hundred (500) dollars, or imprisonment for a term of not less than one (1)

month nor more than six (6) months, or both penalties in the discretion of the Court.”

(f) Section 36 of Act No. 11 of June 23, 1976, as amended, is hereby amended to read as follows:

“Section 36.—Rules and Regulations.—

Every regulation adopted by virtue of this Act, which is not a bylaw, must be approved according to the following procedure, in addition to complying with Act No. 112 of June 30, 1957.

Before recommending that the Secretary of Health give his/her final approval, the Council or the corresponding Examining Board shall hold public hearings. At least twenty-one (21) days before holding a hearing, a public notice with the date, place and nature of said hearing, as well as the place and manner of obtaining additional information concerning the matter to be heard, shall be published in two newspapers of general circulation.

Any interested party may request copies of the proposed regulations and/or the proposed amendments and shall have a reasonable opportunity to submit, verbally or in writing, data, opinions or comments on said proposed regulations or amendments.

The Council or the corresponding Examining Board shall request groups, entities or knowledgeable individuals in the community or in the sectors affected by the regulations or the amendments to participate in the hearings.”

Section 7.06.—Severability.—

If any provision of this Act or its application to any person or circumstance were to be found null, its nullity shall not impair other provisions or applications of the Act which may be kept in effect without

resorting to the provision or application thus rendered null. For this purpose, the provisions of this Act are severable.

Section 7.07.—Effectiveness.—

This Act shall take effect immediately after its approval.

CERTIFICATION

I hereby certify to the Secretary of State that the following Act No.247 (H.B. 4248) of the 7th Session of the 14th Legislature of Puerto Rico:

AN ACT regulate the exercise of the pharmacist profession and the pharmacy technician occupation; to create the Puerto Rico Board of Pharmacy, establish its organization and functions; regulate the manufacture, distribution and dispensing of drugs in the Commonwealth of Puerto Rico; to regulate the interchange for bioequivalent drugs in Puerto Rico; repeal Act No. 282 of May 15, 1945, as amended; repeal subsections (e), (f), (h), (i) and (l) of Section 3, Sections 21, 22, 23, 24, 25, 27, 28, and 29, amend Section 35, and amend Section 36 of Act No. 11 of June 23, 1976, as amended; to fix penalties; and for other purposes,

has been translated from Spanish to English and that the English version is correct.

In San Juan, Puerto Rico, today 21st of August of 2006.

Francisco J. Domenech
Director

