# Republic of the Philippines Congress of the Philippines Metro Manila

Sixteenth Congress

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Begun and held in Metro Manila, on Monday, the twenty-seventh day of July, two thousand fifteen.

# [ REPUBLIC ACT NO. 10918 ]

AN ACT REGULATING AND MODERNIZING THE PRACTICE OF PHARMACY IN THE PHILIPPINES, REPEALING FOR THE PURPOSE REPUBLIC ACT NUMBERED FIVE THOUSAND NINE HUNDRED TWENTY-ONE (R.A. NO. 5921), OTHERWISE KNOWN AS THE PHARMACY LAW

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

# ARTICLE I

# GENERAL PROVISIONS

Section 1. Title. – This Act shall be known as the "Philippine Pharmacy Act".

SEC. 2. Statement of Policy. — The State recognizes the vital role of pharmacists in the delivery of quality health care services through the provision of safe, effective, and quality

pharmaceutical products, pharmaceutical care, drug information, patient medication counseling, and health promotion. The pharmacists' professional services shall, therefore, be promoted as an indispensable component of the total health care system to ensure the physical well-being of the Filipinos.

Hence, the State shall develop and nurture competent, productive, morally upright, and well-rounded pharmacists whose standards of professional practice and service shall be excellent and globally competitive through regulatory measures, programs, and activities that promote and sustain their continuing professional development.

- SEC. 3. Objectives. This Act provides for and shall govern the:
  - (a) Standardization and regulation of pharmacy education;
- (b) Administration of licensure examination, registration, and licensing of pharmacists;
- (c) Supervision, control, and regulation of the practice of pharmacy in the Philippines;
- (d) Development and enhancement of professional competence of pharmacists through continuing professional development, research, and other related activities; and
  - (e) Integration of the pharmacy profession.
- SEC. 4. Scope of the Practice of Pharmacy. A person is deemed to be practicing pharmacy, within the meaning of this Act, when with or without a fee, salary, percentage or other rewards, paid or given directly or indirectly, shall:
- (a) Prepare, compound or manufacture, preserve, store, distribute, procure, sell, or dispense, or both, any pharmaceutical product or its raw materials; or
- (b) Render services, such as clinical pharmacy services, drug information services, regulatory services, pharmaceutical marketing, medication management, or whenever the expertise and technical knowledge of the pharmacist is required; or

- (c) Engage in teaching scientific, technical, or professional pharmacy courses in a school or college of pharmacy; or
- (d) Dispense pharmaceutical products in situations where supervision of dispensing of pharmaceutical products is required; or
- (e) Chemical, biological or microbiological analyses and assay of pharmaceutical products, food/dietary supplements, health supplements, and cosmetics; or
- (f) Physico-chemical analyses for medical devices used in aid of administration of pharmaceutical products; or
- (g) Administration of adult vaccines as approved by the Food and Drug Administration (FDA): Provided, That they shall undergo the training on the safe administration of adult vaccines and management of adverse event following immunization (AEFI) for pharmacists and hold a certificate of training issued by an institution duly accredited by the Professional Regulation Commission (PRC): Provided, further, That the safe administration of vaccines be part of the higher education curriculum for pharmacists; or
- (h) Conduct or undertake scientific research in all aspects involving pharmaceutical products and health care; or
- (i) Provide other services where pharmaceutical knowledge is required.

Activities under paragraphs (a), (b), (c), (d) and (i) are exclusive to licensed pharmacists. However, nothing herein shall be construed as requiring other persons carrying out only the activities under paragraphs (e), (f), (g) and (h) to be licensed pharmacists, subject to any qualification that is imposed by other laws with respect to such particular activity.

All pharmacists are expected to abide by current standards such as the Philippine Practice Standards for Pharmacists, Good Laboratory Practice, Good Distribution Practice, Good Manufacturing Practice and Good Clinical Practice, which are deemed vital in the performance of their roles and functions in different practice areas.

The Professional Regulatory Board of Pharmacy, hereinafter created, subject to the approval of the PRC, as provided for by Republic Act No. 8981, otherwise known as the "PRC Modernization Act of 2000", and in consultation with the integrated and accredited professional organization (APO), may modify the above-enumerated acts, services, or activities, as the need arises, in order to conform to the latest trends and developments in the practice of the pharmacy profession: *Provided*, That such modifications are consistent with the enumeration above.

# SEC. 5. Definition of Terms. - As used in this Act:

- (a) Accredited professional organization (APO) refers to the duly integrated and accredited professional organization of registered and licensed pharmacists, of which there shall be only one (1), as prescribed under Section 41, Article V of this Act;
- (b) Adult vaccines refer to cervical cancer, flu (influenza), pneumococcal, other pre-exposure prophylactic vaccines to be administered to patients aged eighteen (18) years and above, and such other vaccines as may be defined by the Department of Health (DOH) in an administrative issuance;
- (c) Adulterated/Deteriorated pharmaceutical products refer to pharmaceutical products unfit for human consumption, following the standards of quality or purity of which, are as those stated in the *United States Pharmacopeia/National Formulary* and *Philippine Pharmacopeia* in its latest edition or any standard reference for drugs and medicines which are given official recognition as well as those provided for in Republic Act No. 3720, otherwise known as the "Food, Drug, and Cosmetic Act", as amended, and Republic Act No. 9711, known as the "Food and Drug Administration Act of 2009";
- (d) Biopharmaceuticals refer to pharmaceutical products that are used for therapeutic or for in vivo diagnostic purposes, such as vaccines, sera, and drugs derived from life forms using biotechnology. These include proteins, nucleic acids, or living microorganisms where the virulence is reduced and are used for therapeutic or for in vivo diagnostic purposes;

- (e) Brand name refers to the proprietary name given by the manufacturer to distinguish its product from those of competitors;
- (f) Cipher, Code, or Secret Key refers to a method of secret writing or use of characteristic style or symbol by substituting other letter/s or character/s for the letter/s intended, for the purpose of misleading the consumer;
- (g) Compounding refers to the sum of processes performed by a pharmacist in drug preparation including the calculations, mixing, assembling, packaging, or labeling of a drug: (i) as the result of a prescription or drug order by a physician, dentist, or veterinarian; or (ii) for the purpose of, or in relation to, research, teaching, or chemical analysis;
- (h) Continuing professional development (CPD) refers to the inculcation of advanced knowledge, skills, and ethical values in a post-licensure specialized or in an inter- or multidisciplinary field of study for assimilation into professional practice, self-directed research, and/or lifelong learning;
- (i) Cosmetics refer to a substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting the body or keeping them in good condition, as defined under Republic Act No. 9711;
- (j) Counterfeit pharmaceutical products refer to pharmaceutical products which do not contain the amounts as claimed; with wrong ingredients; without active ingredients; or with insufficient quantity of active ingredients, which result in the reduction of the products' safety, efficacy, quality, strength, or purity. These also refer to products that are deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products, including the following:

- (1) The pharmaceutical product itself or the container or labeling thereof or any part of such product, container, or labeling, bearing without authorization; the trademark, trade name, or other identification marks or imprints or any likeness to that which is owned or registered in the Intellectual Property Office (IPO) in the name of another natural or juridical person;
- (2) A pharmaceutical product refilled in containers bearing legitimate labels or marks, without authority; and
- (3) A pharmaceutical product which contains no amount of or a different active ingredient; or less than eighty percent (80%) of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration;
- (k) Dangerous drugs refer to those listed in the: (1) Schedules annexed to the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol; (2) Schedules annexed to the 1971 Single Convention on Psychotropic Substances; and (3) Annex of Republic Act No. 9165, otherwise known as the "Comprehensive Dangerous Drugs Act of 2002", and its amendments;
- (1) Dispensing refers to the sum of processes performed by a pharmacist from reading, validating, and interpreting prescriptions; preparing; packaging; labeling; record keeping; dose calculations; and counseling or giving information, in relation to the sale or transfer of pharmaceutical products, with or without a prescription or medication order;
- (m) *Drugs* refer to pharmaceutical products that pertain to chemical compounds or biological substances, other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals, including the following:
- (1) Any article recognized in the official United States Pharmacopeia/National Formulary, Homeopathic Pharmacopeia of the United States of America, Philippine Pharmacopeia, Philippine National Drug Formulary, British Pharmacopeeia, European Pharmacopeeia, Japanese Pharmacopeeia, and any official compendium or any supplement to them;

- (2) Any article intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease of man or animals;
- (3) Any article, other than food, intended to affect the structure or any function of the human body or animals;
- (4) Any article intended for use, as a component of articles, specified in clauses (1), (2) and (3), not including devices or their components, parts and accessories; and
- (5) Herbal or traditional drugs as defined in Republic Act No. 9502:
- (n) *Emergency cases* refer to life-threatening situations where a patient needs immediate medical attention and treatment, including the occurrence of epidemic or natural calamities;
- (o) Expiration date refers to the end date when the manufacturer can guarantee that a product possesses its claimed potency, efficacy, quality, and safety; after which its sale or distribution is prohibited;
- (p) Filling refers to the act of dispensing or providing medicines in accordance with a prescription or medication order;
- (q) Food/Dietary supplements refer to processed food products intended to supplement the diet that bears or contains one (1) or more of the following dietary ingredients: vitamins, minerals, herbs, or other botanicals, amino acids, and dietary substances to increase the total daily intake in amounts conforming to the latest Philippine-recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders, or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines, as defined under Republic Act No. 9711;
- (r) Generic name refers to the scientifically and internationally recognized name of the active ingredients, as approved by the FDA pursuant to Republic Act No. 6675, otherwise known as the "Generics Act of 1988":

- (s) Health supplement refers to any product that is used to maintain, enhance and improve the healthy function of the human body and contains one (1) or more or a combination of the following: (1) herbal fatty acids, enzymes, probiotics, and other bioactive substances; and (2) substances derived from natural sources, including animal, plant, mineral, and botanical materials in the form of extracts, isolates, concentrates, metabolites, synthetic sources of substances mentioned in (1) and (2). It is presented in dosage forms or in small unit doses such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectibles, eyedrops);
- (t) Household remedies refer to any preparation containing pharmaceutical substances of common or ordinary use to relieve common physical ailments and which may be dispensed without a medical prescription in original packages, bottles or containers, of which the nomenclature has been duly approved by the FDA;
- (u) Institutional pharmacies refer to pharmacies of institutions, organizations, and/or corporations that provide a range of pharmaceutical services, given exclusively to the employees and/or their qualified dependents;
- (v) Internship program refers to a supervised practical experience that is required to be completed for licensure as a registered pharmacist;
- (w) Label refers to a display of written, printed, or graphic matter on the immediate container of any article;
- (x) Labeling materials refer to all labels and other written, printed, or graphic matter: (1) upon any item or any of its containers or wrappers; or (2) accompanying any such item;
- (y) Medical device refers to any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings, for one (1) or more of the specific purposes of: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, or alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy of a physiological process;

supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means, as defined under Republic Act No. 9711;

- (z) Medical mission refers to an activity conducted on normal circumstances of an individual or a group of health care practitioners to provide health services outside the hospital, clinic, and health care facility premises as differentiated from humanitarian missions and relief operations which is conducted during emergency situations such as calamity, war, or natural and man-made disasters;
- (aa) *Medicines* refer to drugs in their appropriate dosage forms, with assured quality, safety and efficacy for humans or animals, or both;
- (bb) Medical representative or professional service representative refers to one who represents any duly authorized manufacturer, distributor, trader, and wholesaler of pharmaceutical products and whose primary duty is to promote their products to duly licensed health professionals;
- (cc) Nontraditional outlets refer to entities licensed by appropriate government agencies to dispense over-the-counter medicines based on an approved list;
- (dd) Online pharmacy services refer to pharmaceutical services of a duly licensed pharmaceutical outlet done over the internet:
- (ee) Over-the-counter (OTC) medicines refer to medicines used for symptomatic relief of minor ailments and which may be dispensed without a prescription;
- (ff) Pharmaceutical establishments refer to entities licensed by appropriate government agencies, and which are involved in the manufacture, importation, exportation, repacking, and distribution of pharmaceutical products to pharmaceutical outlets:

- (gg) Pharmaceutical manufacturers refer to establishments engaged in any or all operations involved in the production of pharmaceutical products including the preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling, preparatory to their storage, sale, or distribution, except the compounding and filling of prescriptions in pharmaceutical outlets;
- (hh) Pharmaceutical marketing refers to any activity undertaken, organized, or sponsored by a pharmaceutical establishment or outlet which is directed at promoting its product;
- (ii) Pharmaceutical outlets refer to entities licensed by appropriate government agencies, and which are involved in compounding and/or dispensing and selling of pharmaceutical products directly to patients or end-users;
- (jj) Pharmaceutical products refer to drugs, medicines, biologicals, pharmaceutical and biopharmaceutical products/ specialties, veterinary products, veterinary biologics and veterinary medicinal products;
- (kk) *Pharmacist* refers to a health professional who has been registered and issued a valid Certificate of Registration (COR) and Professional Identification Card (PIC) by the PRC and the Professional Regulatory Board of Pharmacy;
- (II) Pharmacist-only OTC medicines refer to over-thecounter medicines classified by appropriate government agencies to be obtained only from a licensed pharmacist, with mandatory pharmacist's advice on their selection and proper use;
- (mm) Pharmacy aides refer to persons who assist the pharmacists in the different aspects of pharmacy operation based on established standard operating procedures and processes, with very minimal degree of independence or decision making and without direct interaction with patients;
- (nn) Pharmacy assistants refer to persons who assist the pharmacists in different aspects of pharmacy operation based on established standard operating procedures and processes, with a minimum degree of independence or decision making and may have supervised interaction with patients;

- (∞) Pharmacy technicians refer to persons who assist in compounding and dispensing of medicines in community, hospital, institutional and industrial settings or engaged in other activities under the supervision of the pharmacist as described in Section 39, Article IV of this Act;
- (pp) Philippine Practice Standards for Pharmacists refer to the established national framework for quality standards and guidelines of the practice of pharmacy that respond to the needs of the people who require the pharmacists' services to provide optimal, evidence-based care as formulated by the integrated APO and approved by the Professional Regulatory Board of Pharmacy;
- (qq) *Physician's samples* refer to medicines given to health professionals for promotional purposes only;
- (rr) Prescription/Ethical medicines refer to medicines which can only be dispensed by a pharmacist to a patient, upon the presentation of a valid prescription from a physician, dentist, or veterinarian and for which a pharmacist's advice is necessary;
- (ss) Refilling of a prescription refers to the act of dispensing the remaining balance of medicines ordered in the prescription:
- (tt) Referral refers to the process wherein a pharmacist provides consultative services and conducts preliminary assessment of symptoms and refers the patient to a physician or other health care professional;
- (uu) Referral registry refers to the record book maintained by pharmacists, listing the patients referred to different health facilities for further diagnosis;
- (vv) Refresher program refers to a prescribed study program in an accredited school of pharmacy; and
- (ww) *Telepharmacy services* refer to pharmaceutical services of a duly licensed pharmaceutical outlet done through the use of telephone, teleconferencing, or facsimile.

### ARTICLE II

# THE PROFESSIONAL REGULATORY BOARD OF PHARMACY

- SEC. 6. Creation of the Professional Regulatory Board of Pharmacy. There is hereby created a Professional Regulatory Board of Pharmacy, hereinafter called the Board, under the administrative control and supervision of the PRC, to be composed of a Chairperson and two (2) members, to be appointed by the President of the Philippines from a list of three (3) recommendees for each position ranked in the order of preference and submitted by the PRC from a list of five (5) nominees submitted for each position by the duly integrated APO of pharmacists.
- SEC. 7. Qualifications of the Chairperson and Members of the Board. The Chairperson and members of the Board, at the time of nomination, must:
- (a) Be a citizen of the Philippines and a resident for at least five (5) years;
- (b) Be a duly registered and licensed pharmacist in the Philippines, preferably a holder of a masteral degree in Pharmacy, or its equivalent;
- (c) Have been in the active practice of pharmacy for the past ten (10) years;
- (d) Have not been convicted of a crime involving moral turpitude;
- (e) Be a member in good standing of the APO for at least five (5) years, but not an officer or trustee thereof; and
- (f) At the time of appointment, must neither be a member of the faculty nor an administrative officer of any school, college or university offering degree programs in pharmacy nor has any direct or indirect pecuniary interest or connection in any review center or similar institution.
- SEC. 8. Powers, Functions, and Responsibilities of the Board. The Board shall exercise the following powers, functions, and responsibilities:

- (a) Administer and implement the provisions of this Act;
- (b) Promulgate rules and regulations, administrative orders, and issuances necessary to carry out the provisions of this Act:
- (c) Prepare licensure examination questions, score, and rate the examinations and submit the results thereof to the PRC. The Board shall prepare, adopt, issue, or amend the syllabi or tables of specifications of the subjects in the licensure examination, in consultation with the academe and the Commission on Higher Education (CHED);
- (d) Recommend the issuance, suspension, revocation, or reinstatement of the COR, PIC or Special/Temporary Permits (STP) for the practice of pharmacy;
- (e) Administer oaths in accordance with the provisions of this Act;
- (f) Regulate and monitor the practice of pharmacy in the Philippines, including the practice of subprofessional services such as pharmacy technicians, pharmacy assistants, aides, and other medicine handlers, as described in this Act; adopt measures that may be deemed proper for the enhancement of the profession and the maintenance of high professional, academic, ethical, and technical standards; and conduct ocular inspection of pharmaceutical establishments and higher education institutions (HEIs), in coordination with concerned government agencies;
- (g) Promulgate and prescribe the Pharmacists' Code of Ethics, Code of Technical Standards and Guidelines for the Professional Practice of the Pharmacy Profession, in coordination with the APO:
- (h) Represent the pharmacy profession in all fora involving concerns and issues related to pharmaceutical products and the practice of pharmacy;
- (i) Investigate cases arising from violations of this Act, the rules and regulations promulgated pursuant thereto, the Pharmacists' Code of Ethics, Code of Technical Standards

and Guidelines for the Professional Practice of the Pharmacy Profession, and other Board issuances; issue summons, subpoena ad testificandum and subpoena duces tecum to secure the attendance of witnesses or production of documents, or both, and other evidence necessary for such investigation or hearing; and render decision thereon which shall, unless appealed to the PRC, become final and executory after fifteen (15) days from receipt of notice of judgment or decision;

- (j) Delegate the hearing or investigation of administrative cases filed before the Board, except where the issue or question involves the practice of the profession, in which case, the hearing shall be presided over by at least one (1) member of the Board, to be assisted by a Legal or Hearing Officer of the PRC:
- (k) Conduct, through the Legal Officers of the PRC, summary proceedings on minor violations of this Act, the General Instruction to the Examinees, including the implementing rules and regulations issued by the Board, and to render summary judgment thereon which shall, unless appealed to the PRC, become final and executory after fifteen (15) days from receipt of notice of judgment or decision;
- (l) Issue and promulgate guidelines on CPD, in coordination with the APO;
- (m) Recommend the accreditation of the standardized training programs for and certifications of medical representatives or professional service representatives, pharmacy technicians, pharmacy assistants, pharmacy aides and other medicine handlers covered in Section 39, Article IV of this Act. The Board shall promulgate the criteria and guidelines in the accreditation of training programs and certifications as described above, in coordination with the APO and with other concerned government agencies;
- (n) Accredit Specialty Boards of Pharmacy based on the criteria that it shall establish and prescribe; and
- (o) Perform and discharge such other functions and responsibilities, as may be deemed implied, incidental, and necessary, to preserve the integrity of the pharmacy licensure

examination and to enhance and upgrade the practice of the pharmacy profession in the country.

- SEC. 9. Term of Office of the Members of the Board. The Chairperson and members of the Board shall hold office for a term of three (3) years from the date of appointment or until their successors shall have been qualified and appointed. They may be reappointed in the same office for another term of three (3) years immediately after the expiry of their term: Provided, That no member of the Board shall hold office for more than two (2) terms or not more than six (6) years: Provided, further, That the first Board appointed under this Act shall hold these terms of office: the Chairperson for three (3) years, the first member for two (2) years, and the second member for one (1) year: Provided, finally, That an appointee to a vacancy shall serve only the unexpired portion of the term of office. The Chairperson and members of the Board shall duly take their oath of office before a duly authorized officer.
- SEC. 10. Compensation and Allowances of the Board. The Chairperson and members of the Board shall receive compensation and allowances comparable to the compensation and allowances received by the members of the other existing professional regulatory boards under the PRC, as provided for in the General Appropriations Act.
- SEC. 11. Grounds for Suspension or Removal from Office of the Chairperson or Member of the Board. The President of the Philippines may, upon recommendation of the PRC and after due process, suspend or remove the Chairperson or any member of the Board on any of the following grounds:
- (a) Gross neglect, incompetence, or dishonesty in the discharge of duty;
- (b) Involvement in the manipulation, tampering, or rigging of the licensure examination, its questions or results, or both, and in the disclosure of classified and confidential information pertaining to the licensure examination;
- (c) Conviction of an offense involving moral turpitude by a court of competent jurisdiction; and

 $\begin{tabular}{ll} (d) & Unprofessional, unethical, immoral, or dishonorable \\ conduct. \end{tabular}$ 

The PRC, in the conduct of investigation, shall be guided by Sections 7 and 15 of Republic Act No. 8981, the existing rules on administrative investigation, and the Rules of Court.

SEC. 12. Custodian of its Records, Secretariat and Support Services. – All records of the Board, pertaining to the applications for examinations, administrative and other investigative hearings conducted by the Board, shall be under the custody of the PRC. The PRC shall designate a Secretary who shall provide the Board with secretariat and other support services to implement the provisions of this Act.

### ARTICLE III

### EXAMINATION, REGISTRATION, AND LICENSURE

- SEC. 13. Licensure Examination Requirement. Unless exempted therefrom, all applicants for registration for the practice of pharmacy shall be required to pass a licensure examination, as provided for in this Act and Section 7(d) of Republic Act No. 8981.
- SEC. 14. Qualifications for the Licensure Examination. An applicant for the Pharmacists' Licensure Examination shall establish to the satisfaction of the Board that the following qualifications are met:
- (a) A citizen of the Philippines or of a foreign country which has a law or policy on reciprocity for the practice of the pharmacy profession;
  - (b) Of good moral character and reputation;
- (c) A degree holder of Bachelor of Science in Pharmacy or its equivalent degree conferred by an HEI in the Philippines or an institution of learning in a foreign country duly recognized by the CHED; and
- (d) Has completed an internship program approved by the Board, pursuant to such guidelines as may hereinafter be

promulgated, in consultation with the duly recognized associations of pharmacy schools and the CHED.

SEC. 15. Scope of Examination. – The Pharmacists' Licensure Examination shall cover the following subjects on Pharmacy Science and Practice: Inorganic Pharmaceutical Chemistry, Organic Pharmaceutical Chemistry, Qualitative and Quantitative Pharmaceutical Chemistry, Pharmacognosy and Plant Chemistry, Pharmaceutical Biochemistry, Microbiology and Parasitology, Physical Pharmacy, Biopharmaceutics, Pharmacology and Toxicology, Manufacturing, Quality Assurance and Instrumentation, Pharmaceutical Calculations, Drug Delivery Systems, Hospital Pharmacy, Clinical Pharmacy, Dispensing and Medication Counseling, Pharmaceutical Administration and Management, Public Health, Legal Pharmacy, and Ethics.

The Board, subject to the approval of the PRC, may introduce relevant changes on the subject areas, format, and content of the examination, as well as on the relative weight attributed to each examination subject, as the need arises, and in consultation with the duly recognized associations of pharmacy schools and the CHED.

- SEC. 16. Holding of Examination. The Pharmacists' Licensure Examination shall be given two (2) times a year in places and dates as the PRC may designate in the Resolution providing for the master schedule of all licensure examinations pursuant to Section 7(d) of Republic Act No. 8981.
- SEC. 17. Ratings in the Licensure Examination. In order to be registered and licensed as a pharmacist, a candidate must obtain a general weighted average of seventy-five percent (75%), with no rating lower than fifty percent (50%) in any of the subjects.

An applicant who failed in the licensure examination for the third  $(3^{rd})$  time shall not be allowed to take the next succeeding examinations without having undertaken a refresher program in a duly accredited institution. The Board shall issue guidelines on the refresher program requirement.

- SEC. 18. Report of Rating. The Board shall submit to the PRC the ratings obtained by each candidate within three (3) working days after the last day of the examination, unless extended for just cause. Upon the release of the results of the examination, the PRC shall send by mail the rating obtained by each examinee at the given address using the mailing envelope submitted during the examination.
- SEC. 19. Oath of Profession. All successful candidates in the licensure examination shall take their oath of profession before any member of the Board, officer of the PRC, or any person authorized by law to administer oaths, prior to entering the practice of the pharmacy profession.
- SEC. 20. Issuance of Certificate of Registration and Professional Identification Card. A COR as a pharmacist shall be issued to those who passed the licensure examination, subject to compliance with the registration requirements and payment of the prescribed fees. The COR shall bear the registration number, the date of its issuance, and the signatures of the Chairperson of the PRC and the members of the Board, stamped with the official seals of the PRC and of the Board, certifying that the person named therein is entitled to the practice of the profession, with all the privileges appurtenant thereto. This COR shall remain in full force and effect until suspended or revoked in accordance with this Act.

A PIC bearing the registration number and dates of its issuance and expiry, duly signed by the Chairperson of the PRC, shall likewise be issued to every registrant, upon payment of the prescribed fees. The PIC shall be renewed every three (3) years, upon presentation of the Certificate of Good Standing (COGS) from the APO and proof of completion of the CPD requirements.

SEC. 21. Foreign Reciprocity. — Unless the country or state of which the foreign pharmacist is a subject or citizen, specifically permits Filipino pharmacists to practice within its territorial limits on the same basis as the subjects or citizens of the said foreign country or state under reciprocity and under international agreements, no foreigner shall be

admitted to licensure examinations, given a COR to practice as pharmacist nor be entitled to any of the privileges under this Act.

- SEC. 22. Practice Through Special/Temporary Permit (STP). The practice of pharmacy in the Philippines shall be limited to natural persons only and shall be governed by the provisions of Republic Act No. 8981 and other issuances pertinent thereto: Provided, That any foreign citizen who has gained entry in the Philippines to perform professional services within the scope of the practice of pharmacy, including the following: (a) being a consultant in foreign-funded or assisted projects of the government; (b) being engaged or employed by a Filipino employer or establishment; (c) providing free services in humanitarian missions; and (d) being a visiting faculty member in any field or specialty in pharmacy shall, before assuming such duties, functions and responsibilities, secure an STP from the Board and the PRC, under the following conditions:
- (1) The person is an internationally renowned pharmacist or expert in a field or specialty of pharmacy;
- (2) The person is engaged in the provision of a professional service which is determined to be necessary due to lack of Filipino specialist or expert; and
- (3) The person is required to work with a Filipino counterpart, a natural person who is a registered and licensed pharmacist.
- SEC. 23. Grounds for Non-registration. The Board shall not register any successful examinee who has been:
- (a) Convicted of an offense involving moral turpitude by a court of competent jurisdiction;
- (b) Summarily adjudged by the Board as guilty for misrepresentation or falsification of documents in connection with the application for examination or for violation of the General Instructions to Examinees;

- (c) Found guilty of immoral or dishonorable conduct by the Board;
- (d) Medically proven to be addicted to any drug or alcohol by a medical or drug testing facility accredited by the government; and
- (e) Declared of unsound mind by a court of competent jurisdiction.

In refusing the registration, the Board shall give a written statement setting forth the reasons therefor and shall file a copy thereof in its records. Should ground (d) be proven to be no longer existent, the Board shall issue a Board Resolution allowing the issuance of such COR.

SEC. 24. Reissuance of Revoked Certificate of Registration, Replacement of Lost or Damaged Certificate of Registration, Professional Identification Card or Special/Temporary Permit. — The Board may, upon petition, reinstate or reissue a revoked COR after the expiration of two (2) years from the date of its revocation. The Board may, in its discretion, require the applicant to take another licensure examination. The petitioner shall prove to the Board that there is a valid reason for such reinstatement. For the grant of the petition, the Board shall issue a Board Resolution, to be approved by the PRC.

A duplicate copy of the COR for display in Category B establishments may be issued. Replacement of lost or damaged COR, PIC or STP may be issued in accordance with the pertinent rules that shall be issued thereon.

# ARTICLE IV

# REGULATION OF THE PRACTICE OF PHARMACY

SEC. 25. Vested Rights; Automatic Registration. — All pharmacists registered before the effectivity of this Act shall automatically be registered hereunder, subject to compliance as to future requirements.

The CORs, PICs or STPs held by such persons in good standing shall have the same force and effect, as though they were issued on or after the effectivity of this Act.

SEC. 26. Affixing RPh After a Registered Pharmacist's Name. — Only duly registered and licensed pharmacists shall have the right to affix to one's name, the title "Registered Pharmacist" or "RPh".

SEC. 27. Indication of Information. — A pharmacist shall be required to indicate the serial numbers, the date of expiry of the pharmacist's PIC and APO Certificate of Membership on all pertinent documents signed by him/her.

SEC. 28. Registry of Pharmacists. – The Board and the PRC shall prepare and maintain a registry of the names, residences or office addresses, or both, status of registration and area of practice of all registered pharmacists, which shall be updated annually, in coordination with the APO. This registry shall be made available to the public upon inquiry or request, subject to such guidelines that shall be established therefor.

SEC. 29. Display of Certificate of Registration. — It shall be the duty of every pharmacist engaged in the practice, whether in private or under the employ of another, to display the original copy of one's COR in a prominent and conspicuous place in the drug establishment in which one is employed in a professional capacity as pharmacist. When employed in establishments under Category B, as defined in Section 31 of this Act, the duplicate copy of the pharmacist's COR shall also be displayed therein.

No pharmacist shall knowingly allow the COR to be displayed in an establishment where one is not actually employed as a professional pharmacist.

SEC. 30. Dispensing/Sale of Pharmaceutical Products. – No pharmaceutical product, of whatever nature and kind, shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public, except through a retail drug outlet duly licensed by the FDA.

Prescription drugs and pharmacist-only OTC medicines shall be dispensed only by a duly registered and licensed

pharmacist, except in emergency cases, where the services of a registered and licensed pharmacist are not available: *Provided*, That a report shall be made to the supervising pharmacist within twenty-four (24) hours after the occurrence of the emergency so that product recording in the prescription books can be done.

Compounding and dispensing shall be done only by duly registered and licensed pharmacists, in accordance with current Good Manufacturing Practice, laboratory practice, Philippine Practice Standards for Pharmacists and dispensing guidelines. A registered and licensed pharmacist may refuse to compound, dispense or sell drugs and pharmaceutical products, if not in accordance with this Act and the abovementioned standards.

Licensed manufacturers, importers, distributors, and wholesalers of pharmaceutical products are authorized to sell their products only to duly licensed pharmaceutical outlets.

- SEC. 31. Pharmacist Requirement. Establishments/ outlets which are required to employ and/or retain and maintain the professional services of duly registered and licensed pharmacists shall be classified as follows:
- (a) Category A Pharmaceutical establishments/outlets where the direct and immediate control and supervision of a duly registered and licensed pharmacist is required, per establishment, whether in-store or online, including:
- (1) Pharmaceutical establishments/outlets selling or otherwise making available to the consuming public prescription/ethical medicines, combination products (medical device and drugs) classified as drugs according to the primary intended mode of action, pharmacist-only OTC medicine, whether owned by the government or by a private person or firm, whether sold at wholesale or retail;
- (2) Establishments involved in the manufacture, importation, exportation, distribution, and sale of combination products (medical device and drugs) classified as drugs according to the primary intended mode of action;
- (3) Departments/Divisions/Units of pharmaceutical laboratories, pharmaceutical manufacturing laboratories, or other

establishments with processes involving the preparation, manufacture, assay, regulation, product research and development, quality control, repacking, importation, exportation, distribution, sale or transfer of pharmaceutical products in quantities greatly in excess of single therapeutic doses; and

- (4) Government units, including local government, city, first to third class municipal health units, nongovernment organizations and/or associations involved in the procurement, distribution, dispensing and storage of pharmaceutical products;
- (b) Category B Pharmaceutical establishments/outlets where the supervision and oversight of a duly registered and licensed pharmacist is required under pertinent provisions of law, including:
- Retail outlets selling household remedies and OTC drugs as differentiated from the pharmacist-only OTC medicines;
- (2) Satellite institutional pharmacies providing medicines solely to employees of their respective companies or the employees' qualified dependents, or both; or members of a duly registered organization or institution;
- (3) Fourth, fifth and sixth class municipal health units involved in the procurement, distribution, dispensing, and storage of pharmaceutical products;
  - (4) Institutions providing telepharmacy services; and
- (5) Nontraditional outlets of pharmaceutical products: *Provided*, That no prescription medicines and pharmacist-only OTC medicines are sold.

The FDA, in coordination with the Board, and the approval of the PRC, may add to, delete, reclassify, or modify the above list of establishments, as the need arises, in order to keep pace with the developments in the pharmacy practice.

A pharmacist working in a Category A establishment may be allowed to simultaneously work or render pharmacy services in Category B establishments, the maximum number of hours of which shall be determined, in accordance with such guidelines as may be established therefor by the Board, in coordination with the FDA, and other agencies, establishments, institutions, and regulatory bodies.

Procurement, storage, distribution, or dispensing of any pharmaceutical product in the national government and local government units shall be made only under the supervision of a duly registered and licensed pharmacist.

All units or sub-units of establishments, institutions, and regulatory bodies whether government or private with functions and activities that are exclusive for pharmacists, as defined in Section 4, paragraphs (a), (b), (c), (d) and (i), shall be headed and managed by a qualified duly registered and licensed pharmacist: *Provided*, That an appointment in government service shall comply with the provisions of other pertinent laws.

SEC. 32. Responsibility for Quality of Pharmaceutical Products. — It shall be the duty of a duly licensed and registered pharmacist of a pharmaceutical establishment and outlet to ensure that all pharmaceutical products conform to standards of safety, quality and efficacy, as provided for in this Act and other pertinent rules and regulations and issuances. Owners, managers, or pharmacists in charge of the operation of pharmaceutical establishments and outlets shall be held jointly responsible for nonconformance with these standards.

It shall be unlawful for any person to manufacture, prepare, sell, or dispense any pharmaceutical product under a fraudulent name, or pretense or to adulterate any pharmaceutical product offered for sale.

In cases of pharmaceutical products sold in their original package, the seal of which has not been broken or tampered with, the liability that may arise because of their quality and purity rests upon the manufacturer or importer, the distributor, representative, or dealer who is responsible for their distribution or sale.

SEC. 33. Filling and Partial Filling of Prescription. – All prescriptions and pharmacist-only OTC medicines shall be filled, compounded and dispensed only by a registered and licensed

pharmacist, in accordance with the Philippine Practice Standards for Pharmacists, Dispensing Guidelines and other standards pertaining to purity, safety and quality. Completely filled prescriptions should be surrendered to the pharmacist for recording.

Partial filling of prescription less than the total quantity indicated in the prescription shall be allowed, subject to dispensing guidelines as provided in the immediately preceding paragraph. It is the responsibility of the pharmacist dispensing the last quantity completing the prescription to keep the prescription according to proper prescription recording guidelines.

Prescription medicines may be dispensed only by a duly registered and licensed pharmacist and only with a valid prescription of a physician, dentist, or veterinarian.

SEC. 34. Physician's Sample. – Pharmaceutical products given or intended to be given free to any health professional by a manufacturer or distributor or its professional service representative as part of its program or promotion shall not be sold to any pharmaceutical outlet or the consuming public.

The statement "Sample, Not for Sale", or its equivalent, shall appear conspicuously on the primary and secondary packaging of the drug or combination products (medical device and drug) classified as drug according to the primary intended mode of action to be given. It shall be unlawful to remove, erase, deface or mark the original labels of samples.

Pharmaceutical products classified as antimicrobials, including anti-TB medicines and other classifications of medicines, as may be prescribed by the FDA, shall not be given or distributed as physician's samples.

SEC. 35. Prohibition Against the Use of Cipher, Codes, or Unusual Terms in Prescriptions and Prescription Substitution. — Pharmacists shall not compound or dispense prescriptions, recipes, or formulas which are written in ciphers, codes or secret keys or prescriptions of pharmaceutical products with unusual names which differ from those in standard pharmacopeias or formularies.

The pharmacist dispensing or compounding prescriptions shall not substitute the medicine called for in the prescription with any other drug, substance or ingredient, without prior consultation with, and written consent of the person prescribing, except in accordance with Republic Act No. 6675, as amended, otherwise known as the "Generics Act of 1988", and other pertinent laws and regulations.

SEC. 36. Label of Dispensed Medicines. — Upon every box, bottle, or package of medicines compounded or dispensed by a registered and licensed pharmacist based on prescription, there shall be pasted, affixed, or imprinted a seal or label bearing, among others, the name of patient and generic name of drug; brand name, if any, strength, expiry date, directions for use; and name and address of pharmacy, name of the doctor, the dispensing pharmacist and other requirements prescribed in the Philippine Practice Standards for Pharmacists and Dispensing Guidelines, Republic Act No. 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008", its implementing rules and regulations and such other guidelines that may be promulgated by the Board.

Auxiliary labels containing special pharmacists' instructions for the patient shall be required as prescribed for dangerous drugs, external-use-only drugs, drugs with special storage and administration instructions and such other drugs as may be required by law.

SEC. 37. Recording of Patient Medication Profile. — All prescriptions dispensed in the pharmacy shall be recorded in an appropriate recording system indicating therein, among other things, the name and address of the patient, name of prescriber, generic name and brand, dosage strength, quantity of drug and initials of pharmacist. It shall be open for inspection by the representatives of the Board or the FDA, or both, at any time of the day, when the pharmacy is open, and must be kept for a period of not less than two (2) years after the last entry.

All required information on dangerous drugs dispensed by a pharmacy shall be recorded in the Dangerous Drugs Book or an equivalent recording system as required by Republic Act No. 9165 and other applicable laws and issuances.

All referrals such as tuberculosis patients undertaken by the pharmaceutical outlets shall be recorded in the Referral Registry and shall be open for inspection by the Board, or representative of the Department of Health (DOH) or the FDA, or both, at any time of the day when the pharmacy is open, and must be kept for a period of not less than two (2) years after the last entry.

SEC. 38. Requirements for the Opening and Operation of Retail Pharmaceutical Outlet or Establishment. — The opening of a retail pharmaceutical outlet or establishment shall be subject to requirements provided for in this Act and the rules and regulations prescribed by the FDA.

The application for the opening and operation of a retail drug outlet or other similar business establishments shall not be approved, unless applied for by a Filipino registered and licensed pharmacist, either as owner or as pharmacist-in-charge, pursuant to the provisions of this Act.

SEC. 39. Handling of Pharmaceutical Products by Persons Other Than a Pharmacist. — For the purpose of this section, persons handling pharmaceutical products, other than the pharmacist, which shall include pharmacy owners who are non-pharmacists, medical representatives or professional service representatives, pharmacy support personnel, pharmacy technicians, pharmacy assistants, pharmacy aides, persons who assist pharmacists in any part of a pharmacy operation, or any other person performing functions involved in the handling of pharmaceutical products, shall be duly certified by appropriate government agencies after undergoing an accredited training program.

No person, except pharmacy graduates, shall be allowed to render such services without undergoing a comprehensive standardized training program: *Provided*, That the job description is defined in the implementing rules and regulations of this Act.

SEC. 40. Administration of Adult Vaccines. — In addition to the requirement provided in Section 4, paragraph (g) of this Act, licensed and trained pharmacist who shall administer adult vaccines shall ensure that the vaccine to be administered

shall have a doctor's prescription which is not more than seven (7) days old and submit a monthly vaccination report and AEFI report to DOH regional offices using the prescribed form.

### ARTICLE V

### ACCREDITED PROFESSIONAL ORGANIZATION

SEC. 41. The Integrated and Accredited Professional Organization (APO) of Pharmacists. – The pharmacy profession shall be integrated into one (1) national organization registered with the Securities and Exchange Commission (SEC) which shall be recognized by the Board and the PRC as the one and only integrated and accredited professional organization of pharmacists.

A pharmacist duly registered with the Board shall automatically become a member of the integrated and accredited professional organization of pharmacists, and shall receive the benefits and privileges appurtenant thereto upon payment of the required fees and dues.

Membership in the integrated APO shall not be a bar to membership in other associations of pharmacists.

SEC. 42. Membership to the Integrated and Accredited Professional Organization. — All registered pharmacists must be members of the APO and must maintain membership throughout the duration of the practice of the profession. The PIC shall not be renewed if the requirements for membership with the APO are not met including credit units for attendance to duly accredited CPD.

All pharmacy support personnel must be registered as affiliate members of the APO and must likewise maintain membership throughout the duration of employment in pharmaceutical establishments and outlets.

SEC. 43. Specialty Boards in Various Areas of Pharmacy Practice. — Specialty Boards in various areas of pharmacy practice shall be created, subject to accreditation by the Board and the PRC. The Board shall issue guidelines in the accreditation of specialty boards in various areas of pharmacy practice, which shall include the standards of

practice within different specialties, qualifications, and requirements for the certification of practitioners under each specialty, among others.

### ARTICLE VI

VIOLATIONS, ADMINISTRATIVE SANCTIONS, AND PROCEDURES

- SEC. 44. Revocation or Suspension of the Certificate of Registration and Cancellation of Special/Temporary Permit. The Board shall have the power, upon notice and hearing, to revoke or suspend the COR of a registered pharmacist or to cancel an STP of a foreign pharmacist on any of the following grounds:
- (a) Violation of any provision of this Act, its rules and regulations, the Pharmacists' Code of Ethics, Code of Technical Standards for the Professional Practice of the Pharmacy Profession, Code of Good Governance and all other guidelines, policies and regulatory measures of the Board and/or the PRC relating to the practice of the pharmacy profession;
- (b) Conviction of an offense involving moral turpitude by a court of competent jurisdiction;
- (c) Unprofessionalism, immorality, malpractice, incompetence, gross negligence, or imprudence in the practice of the profession;
- (d) Fraud or deceit in the acquisition of the COR, PIC or STP, or renewal thereof;
- (e) Allowing the COR to be used or displayed in establishments where the pharmacist is not actually employed and practicing;
- (f) Addiction to alcoholic beverages or to any habit-forming drug rendering a pharmacist incompetent to practice the profession as provided for in Section 23 hereof;
- (g) Aiding or abetting the illegal practice of a non-registered and licensed person;

- (h) Insanity or any mental disorder that would render the person incompetent to practice pharmacy;
- (i) False, extravagant, or unethical advertisements and endorsements of pharmaceutical products, pharmaceutical outlets and establishments where the pharmacist's name or the pharmacist's professional organization and similar information, or both, are used;
- (j) Manufacture, sale, offering for sale of counterfeit, spurious, substandard and falsified pharmaceutical products and committing other acts in violation of Republic Act No. 9165 and Republic Act No. 8203, otherwise known as the "Special Law on Counterfeit Drugs";
- (k) Illegal manufacture, sale, possession, dispensing of dangerous drugs and other acts in violation of Republic Act No. 9165, and other applicable laws and issuances;
- (I) Committing acts in violation of Section 6 of Presidential Decree No. 881, entitled "Empowering the Secretary of Health to Regulate the Labeling, Sale and Distribution of Hazardous Substances" and Section 11 of Republic Act No. 3720, as amended;
- (m) Practicing pharmacy with a suspended COR or expired PIC;
- (n) Unauthorized dispensing of pharmaceutical products through unregistered online services or direct selling businesses; and
- (o) Being found guilty of immoral, unprofessional, or dishonorable conduct by the Board.

### ARTICLE VII

## PENAL PROVISIONS

SEC. 45. *Penal Provisions*. – Any person who shall commit any of the following acts shall, upon conviction, be sentenced to pay a fine of not less than two hundred fifty

thousand pesos (P250,000.00), but not exceeding five hundred thousand pesos (P500,000.00) or imprisonment of not less than one (1) year and one (1) day but not more than six (6) years, or both, at the discretion of the court:

- (a) Commission of any act in violation of Sections 30 and 31 of this Act;
- (b) Allowing the display of one's COR in a pharmaceutical establishment where the pharmacist is not employed and practicing;
- (c) Displaying of the pharmacist's COR by pharmacy owners/operators in a pharmaceutical establishment where the pharmacist is not employed and practicing;
- (d) Dispensing or allowing the dispensing or offering for sale of prescription drugs or pharmaceutical products in a place not licensed by the FDA as a pharmaceutical outlet;
- (e) Dispensing of prescription and pharmacist-only OTC pharmaceutical products by a person other than those under the direct and immediate supervision of a duly registered and licensed pharmacist;
- (f) Allowing the dispensing of prescription and pharmacistonly OTC pharmaceutical products, without the direct and immediate supervision of a duly registered and licensed pharmacist;
- (g) Compounding and dispensing not in accordance with current Good Manufacturing Practice, Good Laboratory Practice and Philippine Practice Standards for Pharmacists, and such other standards and guidelines issued by the Board;
- (h) Selling of prescription and pharmacist-only OTC drugs by manufacturers, importers, and wholesalers to unlicensed pharmaceutical outlets and other establishments;
- (i) Substituting prescription drugs which are not generically equivalent to what was on the prescription, without the consent of the prescriber or not in accordance with Republic Act No. 6675;

- (j) Forcing, coercing, or intimidating a duly registered and licensed pharmacist to compound or dispense medical and pharmaceutical products in violation of the provisions of this Act:
- (k) Preparing and compounding of pharmaceutical products in quantities greatly in excess of single therapeutic doses, without the presence and supervision of a duly registered and licensed pharmacist;
- (l) Noncompliance with the labeling requirements for dispensed medicines by a pharmaceutical outlet;
- (m) Manufacturing and selling of pharmaceutical products under fraudulent name or address, or both;
- (n) Adulterating and misbranding of pharmaceutical products;
- (o) Manufacturing and selling of unsafe, substandard and counterfeit pharmaceutical products;
- (p) Operating an unlicensed pharmaceutical outlet such as online pharmacy service or direct selling not authorized by the FDA;
- (q) Operating a Category A establishment which opens for business without a duly registered and licensed pharmacist;
- (r) Operating a Category B establishment without the supervision and oversight of a duly registered and licensed pharmacist;
- (s) Practicing pharmacy with an expired, suspended or revoked license;
- (t) Filling and refilling of prescription and pharmacist-only OTC pharmaceutical products by a person other than a duly registered and licensed pharmacist without the direct and immediate supervision;
- (u) Dispensing prescription drugs and pharmacist-only OTC drugs by rural health units without the supervision of a duly registered and licensed pharmacist; and

- (v) All other acts or omissions analogous to the foregoing.
- SEC. 46. Other Penalties. Any person who shall commit any of the following acts shall, upon conviction, be sentenced to pay a fine of not less than one hundred thousand pesos (P100,000.00), but not exceeding two hundred thousand pesos (P200,000.00) or imprisonment of not less than thirty (30) days but not more than one (1) year, or both, at the discretion of the court:
- (a) Affixing of the title "RPh" by a person who is not a duly registered and licensed pharmacist;
- (b) Practicing the pharmacy profession in the Philippines without a valid COR, PIC or STP;
- (c) Non-indication of a pharmacist of his/her COR and professional tax receipt numbers in official documents requiring such information:
- (d) Refusal to display the COR of the pharmacist in a prominent and conspicuous place in the establishment and outlet where the pharmacist is employed and practicing;
- (e) Noncompliance by a duly registered and licensed pharmacist with the requirements on the filling of prescription;
- (f) Noncompliance by a duly registered and licensed pharmacist on the requirements for partially-filled prescription;
  - (g) Selling of physician's samples;
- (h) Distribution of antimicrobials, including anti-TB drugs and other product classification as may be prohibited by law as physician's samples;
- (i) Removal, erasure and alteration of mark or label of physician's sample:
- (j) Use of cipher, codes, or secret keys or unusual names or terms in prescriptions;
- (k) Filling of prescriptions where cipher, codes, or secret keys or unusual names or terms are used;

- (l) Noncompliance with labeling requirements for dispensed medicines;
- (m) Noncompliance with the requirements on the keeping of record books by a pharmaceutical outlet;
- (n) Employment of personnel in a pharmacy or pharmaceutical operation without the required training and certification;
- (o) Refusal of a non-pharmacist owner/operator of a pharmaceutical outlet to undergo training and certification;
- (p) Refusal by the owner/operator to allow and require duly registered and licensed pharmacists and pharmacy support personnel to undergo CPD, training and certification;
- (q) Rendering dispensing-related services by nonpharmacists in a pharmaceutical outlet without undergoing the required training and certification;
- (r) Dispensing pharmaceutical products in medical missions without the supervision of a duly registered and licensed pharmacist;
- (s) Noncompliance with the required training and certification of professional service or medical representatives or professional service representatives, pharmacy technicians, pharmacy assistants, pharmacy aides, pharmacy clerks, and other medicine handlers of pharmaceutical products. Both the medical representatives or professional service representatives, pharmacy technicians, pharmacy assistants, pharmacy aides, pharmacy clerks, or medicine handlers and the pharmaceutical establishment and outlet employing any such individual shall be held jointly liable; and
- (t) Violation of any provision of this Act and its rules and regulations not aforementioned above.

Any person, other than the citizens of the Philippines, having been found guilty of any violation as provided for in this section and the preceding section shall, after having paid the fine or having served the sentence, or both, when so adjudged, shall also be subject to immediate deportation.

The penalties and liabilities herein provided shall be without prejudice to other sanction/s that may be imposed for violation of other applicable laws, policies, rules and regulations.

The owner/operator of the pharmaceutical establishments/ outlets and the duly registered and licensed pharmacists/ pharmacy support personnel are jointly liable for the willful violation of any provision of this Act.

## ARTICLE VIII

### FINAL PROVISIONS

- SEC. 47. Enforcement. It shall be the primary duty of the Board and the PRC to effectively enforce the provisions of this Act. All duly constituted law enforcement agencies and officers of the national, provincial, city or municipal government or of any political subdivision thereof shall ensure the effective enforcement and implementation of the provisions of this Act.
- SEC. 48. Appropriations. The Chairperson of the PRC shall immediately include in its programs the implementation of this Act, the funding of which shall be charged against their current years' appropriations and thereafter, in the annual General Appropriations Act.
- SEC. 49. Transitory Provisions. The incumbent Chairperson and members of the Board shall, in an interim capacity, continue to function as such until the Chairperson and members of the new Board, created under this Act, shall have been appointed and qualified.
- SEC. 50. Implementing Rules and Regulations. Within one hundred twenty (120) days after the approval of this Act, the Board, subject to the approval by the PRC, and in consultation with the APO, shall formulate and issue the rules and regulations to implement the provisions of this Act.
- SEC. 51. Separability Clause. If any clause, provision, paragraph or part hereof shall be declared unconstitutional or invalid, such declaration shall not affect, invalidate, or impair the other provisions otherwise valid and effective.

SEC. 52. Repealing Clause. — Republic Act No. 5921, as amended, is hereby repealed. All other laws, presidential decrees, executive orders and other administrative issuances or parts thereof which are contrary to or inconsistent with the provisions of this Act are hereby repealed, amended, or modified accordingly.

SEC. 53. *Effectivity*. — This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in a newspaper of general circulation.

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Approved.

FRANKLIN M. DRILON President of the Senate FELICIANO BELMONTE IR

Speaker of the House of Representatives

This Act was passed by the House of Representatives as House Bill No. 5616 on May 23, 2016 and adopted by the Senate as an amendment to Senate Bill No. 2436 on May 30, 2016.

OSCAR S. YABES Secretary of the Senate MARILYN B. BARUAY, AP Secretary General

House of Representatives

Approved:

# BENIGNO S. AQUINO III

President of the Philippines

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Without the signature of the President In accordance with Article VI, Section 27 (1) of the Constitution.