H. No. 5616 S. No. 2436 ; Manila Bulletin (August 01, 2016); 112 OG No. 34, 5483 (August 22, 2016)

[REPUBLIC ACT NO. 10918, July 17, 2016]

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:

(l) *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 Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia,* 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;