

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

FIFTEENTH CONGRESS

Second Regular Session

HOUSE BILL NO. 5370

03 OCT 2011
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Introduced by **Honorable Anthony Rolando T. Golez, Jr.**

EXPLANATORY NOTE

The State recognizes the right of the people to health. Assuring the delivery of the right of the people to health necessarily includes the proper dispensation of medicines. In this regard, the practice of the profession of pharmacy comes in. Said profession plays a very important role in ensuring that Filipinos will be given the proper health care. Ironically, even with such a significant role, the practice of the profession of pharmacy has been neglected; the laws governing it have not been updated.

The existing Pharmacy Law, R.A. No. 5921, is no longer responsive to the requirements of pharmacists and the needs of the general public. The foregoing proposed measure aims to enable Filipino pharmacists to catch-up in the world arena in the practice of the profession of pharmacy. It likewise ensures the proper dispensation of medicines to Filipinos; making sure that our countrymen will have proper health care in all related aspects.

The foregoing bill promotes the professional services rendered by pharmacists as a vital part of the entire healthcare system in the Philippines. It provides the development and promotion of a competent and productive practice of the profession of pharmacy through the adoption of measures, programs, and activities that foster the pharmacists' continuing professional growth.

Approval of the bill is earnestly sought.

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HOUSE BILL NO. 5370

Introduced by **Honorable Anthony Rolando T. Golez, Jr.**

**"AN ACT REGULATING THE PRACTICE
OF PHARMACY IN THE PHILIPPINES,
REPEALING FOR THE PURPOSE
REPUBLIC ACT NO. 5921, THE PHARMACY LAW,
AS AMENDED, AND FOR OTHER PURPOSES."**

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

Section 1. Short Title. This Act shall be known as the "Philippine Pharmacy Act of 2011".

Section 2. Declaration of Policy. It is a State policy to protect and promote the right to health of the people and instill health consciousness among them. The state recognizes the important role of pharmacists in providing quality healthcare. The professional service rendered by pharmacists shall be promoted as a vital part of the entire healthcare system in the Philippines. The state shall develop and promote a competent and productive practice of the profession of pharmacy through the adoption of measures, programs, and activities that foster the pharmacists' continuing professional growth.

Section 3. Definition of Terms. The following terms, as used in this Act, shall mean:

- (a) *Biologic Products* - microorganisms, sera, toxins and similar products used for the prevention or cure of human diseases.
- (b) *Brand Name* - the proprietary or trade name given by the manufacturer to distinguish its product from those of the competitors.
- (c) *Cipher* - a method of secret writing that substitutes other letters or characters for the letter intended or transpose the letter after arranging them in blocks or

squares.

- (d) *Code* - a system of words or other symbols arbitrarily used to represent words.
- (e) *Compounding* - the preparation, mixing, assembling, packaging, or labeling of a drug (i) as the result of a prescription or drug order by a physician, dentist, optometrist, or veterinarian, based on the said practitioner-patient-pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or in relation to, research, teaching, or chemical analysis and not for sale or dispensing.
- (f) *Cosmetics* - shall refer to (i) products intended to be applied, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body, or any part thereof for cleansing, beautifying, promoting attractiveness or improving the appearance, or (ii) ingredients or other substances intended for use as a component of any such product.
- (g) *Counterfeit drug, medicine, pharmaceutical* – shall refer to medicinal products with the correct ingredients but not in the amounts as provided, wrong ingredient, without active ingredient/s, with insufficient quantity of active ingredient, which result in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug that is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to:
 - (i) the drug itself or the container or labeling thereof or any part of such drug, container, or labeling bearing without authorization the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark and Technology Transfer (BPTTT) in the name of another natural or juridical person;
 - (ii) a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used;
 - (iii) an imported drug product not registered with the Food and Drug Administration (FDA), except drugs brought in the country for personal use as confirmed and justified by accompanying medical records; and
 - (iv) a drug which contains no amount of 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.
- (h) *Dangerous drugs* – shall refer to those listed in the Schedules annexed to the 1961 Single Convention on Narcotic Drugs as amended by the 197 Protocol, and in the Schedules annexed to the 1971 Single Convention on Psychotropic

Substances as enumerated in the attached annex in Republic Act No. 9165, which is an integral part of the Act.

- (i) *Devices* - any instrument, apparatus, implement, machine, implant, in vitro reagent or calibrator, software, material or other similar or related article:

(a) intended by the manufacturer to be used, along or in combination, for human beings for one or more of the specific purpose(s) of:

(i) diagnosis, prevention, monitoring, treatment, alleviation of diseases of diseases,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury

(iii) investigation, replacement or modification or support of the anatomy of a physiological process,

(iv) supporting or sustaining life,

(v) control of conception,

(vi) disinfection of medical devices,

(vii) providing information for medical or diagnostic purposes by means of an in vitro examination of specimen derived from the human body; and

(b) which 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 their intended function by such means.

- (j) *Dispensing* - a process whereby a pharmacist receives and checks a valid prescriber's medication order or prescription, and makes available drugs and medicines, with advice on their proper use and other relevant information.

- (k) *Drugs and Medicines* - chemical compounds or biological substances, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including but not limited to:

(i) any article recognized in the official United States Pharmacopoeia, National Formulary, official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, and any official compendium or any supplement to them;

(ii) any article intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease of man and animals;

- (iii) any article other than food intended to affect the structure or any function of the human body or animals;
 - (iv) any article intended for use as a component of articles specified in clauses (i), (ii), and (iii) not including devices or their components, parts, accessories; and
 - (v) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are: (a) recognized in the Philippine National Drug Formulary; (b) intended for use in the treatment, or cure or mitigation of disease symptoms, injury or body defects in humans; (c) other than food, intended to affect the structure or any function of the human body; (d) in finished or ready-to-use dosage form; and (e) intended for use as a component of any of the articles specified in clauses (a), (b), (c) or (d).
- (l) *Drug or Pharmaceutical Laboratory or Pharmaceutical Manufacturing Laboratory* - an establishment where pharmaceutical products, proprietary medicines, or pharmaceutical specialties are formulated, prepared, compounded, and standardized.
- (m) *Drug Establishments* - FDA-registered companies involved in the manufacture, importation, repacking, and/or distribution of drugs or medicines.
- (n) *Drug Outlets* - drugstores, pharmacies, and other business establishments which are registered with the FDA and which legally sell drugs and medicines.
- (o) *Drugstore or Pharmacy* - a place or establishment licensed by FDA where drugs, chemicals, pharmaceutical products, specialties, and devices are legally sold at retail or wholesale and where medical, dental, and veterinary prescriptions are compounded and dispensed.
- (p) *Expiration Date* - the date after which the product is not expected to possess its claimed potency, efficacy, quality, and safety; and after which it is not legal to sell or distribute or use the said product.
- (q) *Filling of a prescription* - the act of dispensing or giving out of medicines in accordance with the doctor's order.
- (r) *Household Remedies* - any preparation containing pharmaceutical substances of common or ordinary use to relieve common physical ailments which may be dispensed without a medical prescription in original packages, bottles or containers, the nomenclature of which has been duly approved by FDA in the process of registration as defined in FDA AO No.115 s. 1991)
- (s) *Generic Name* - the scientifically and internationally recognized name of the active ingredient/s as approved by the Food and Drug Administration.

- (t) *Label* - a display of written, printed or graphic information upon the immediate container, or attached to or accompanying any pharmaceutical products.
- (u) *Labeling* - 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.
- (v) *Over-the-counter drugs* - drugs used for symptomatic relief of minor ailments which may be dispensed without a prescription.
- (w) *Pharmaceutical products or Pharmaceutical specialties* - drugs, preparations, or mixture of drugs under a brand or generic name and intended for the cure, mitigation, treatment, or prevention of disease in man or animals.
- (x) *Pharmacist-only over-the-counter drugs* - FDA-classified over-the-counter drugs and/or substances which should only be obtained from the drugstore or pharmacy with mandatory pharmacist's advice on their selection and proper use.
- (y) *Person* - includes an individual, partnership, corporation, or any juridical entity.
- (z) *Pharmaceutical marketing* - any activity undertaken, organized or sponsored by a drug establishment which is directed at promoting the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through direct personal contact and all media, including the internet.
- (aa) *Pharmacy Assistants* - persons who assist pharmacists in dispensing medicines in community, hospital, industrial settings and in other activities, such as, but not limited to medical missions, under the supervision of the pharmacist and as described in Sections 17 and 42 of this Act.
- (bb) *Physician's samples* - medicines given to a physician for free for promotional purposes.
- (cc) *Prescription drugs* - drugs which can only be dispensed by a pharmacist to a patient upon the presentation of a valid prescription from a physician, dentist, optometrist or veterinarian and for which pharmacist's advice on their proper use is necessary.
- (dd) *Refilling of a prescription* - act of dispensing or giving out the remaining balance of medicines ordered in the prescription when the whole quantity ordered is not yet completely filled.
- (ee) *Secret Keys* - characteristic style or symbols kept from the knowledge of others or disclosed confidentially to a few individuals.

Section 4. Enforcement. The Professional Regulatory Board of Pharmacy, as hereby created, and the Professional Regulation Commission are the bodies responsible for the implementation of the provisions of this Act.

Section 5. The Board of Pharmacy and its Composition. The Professional Regulatory

Board of Pharmacy (hereinafter referred to as "Board") is hereby created. The Board shall be under the administration, control, and supervision of the Professional Regulation Commission (hereinafter referred to as "Commission"). The Board shall be composed of a Chairman and four (4) Members. The Chairman and Members shall represent the areas of practice of community, hospital, manufacturing, academe, and government service. Provided that, at any given time, there is one (1) Member of the Board or the Chairman who is a lawyer. The Chairman and Members shall be appointed by the President of the Philippines, upon recommendation from the list of nominees submitted by the Accredited Integrated National Organization for Pharmacists, as hereby created.

Section 6. *Qualifications of Board Members.* To be appointed as Chairman and Member of the Board of Pharmacy, the person must be:

- (a) A citizen of the Philippines and a resident for at least five (5) years.
- (b) A duly registered pharmacist, preferably a holder of a Master of Science in Pharmacy, or its equivalent degree and has been in the practice of pharmacy for at least ten years, unless such Member is the member who is a lawyer as provided for in the preceding Section.
- (c) Of good moral character with a valid certificate of registration, valid professional identification card and preferably with teaching experience; and preferably representing each field of practice.
- (d) At the time of appointment, not a member of the faculty or administrative office of any school, college or university offering degree programs in pharmacy nor connected in a review school or center; nor has any direct or indirect pecuniary interests in any school, college, or any institution offering pharmacy.
- (e) A member of good standing for at least five (5) years of the accredited integrated national pharmacy association but, at the time of nomination, not an officer or trustee thereof.

Section 7. *Term of Office of Board Members.* The Chairman and the Members of the Board shall hold office for three (3) years after appointment or until their successors shall have been appointed and duly qualified. Provided, that the Chairman or any Member may only be re-appointed once and in no case shall he serve for more than six years.

Section 8. *Compensation of the Board of Pharmacy.* As provided for in R.A. No. 8981, known as the "PRC Modernization Act of 2000", the Members of the Board shall receive allowances and benefits equivalent to at least two salary grades lower than the salary grade of a Commissioner in the Commission, while the Chairman of the Board shall receive a monthly compensation equivalent to two steps higher than the Members of the Board. The Chairman and Members of the Board shall be entitled to other allowances and benefits provided under existing laws.

Section 9. *Powers, Functions and Duties of the Board.* The Board shall exercise the following powers, functions, and duties:

- (a) Conduct licensure examination for pharmacists.
- (b) Approve the registration of pharmacists and the certification of drug handlers.
- (c) Prepare, adopt, and issue the Table of Specifications for the subjects in the board licensure examination for pharmacists in consultation with the academe; determine and prepare the questions therefor; score and rate the examination papers with the name and signature of the Board member concerned appearing thereon and submit the results in all subjects duly signed by the members of the Board to the Commission no later than three (3) days from the last day of examination unless extended by the Commission for justifiable causes.
- (d) Review or amend the scope of licensure examination.
- (e) Add, delete, modify the scope, definition and standards of practice of pharmacy.
- (f) Reprimand any pharmacist, suspend, or revoke his/her certificate of registration on the grounds as provided for in Sec. 46 hereof, after a formal administrative investigation.
- (g) Promulgate from time to time the necessary rules and regulations for the effective enforcement of this Act.
- (h) Monitor the conditions affecting the practice of pharmacy in the Philippines and adopt measures that may be deemed proper for the enhancement of the profession and the maintenance of high professional, academic, ethical and technical standards.
- (i) Verify or confirm the qualifications and conditions of pharmacists employed in drugstores, hospital pharmacies, drug or pharmaceutical laboratories, drug traders, importers, cosmetics and medical device establishments for which the Board may designate inspectors from the Food and Drug Administration and other related institutions for such purpose.
- (j) Investigate cases arising from violations of this Act, the rules and regulations promulgated thereunder and the Pharmacist's Code of Ethics, technical standards, and other Board issuances and for this purpose, may issue summons, subpoenas to respondents and witnesses to compel their attendance in such investigations or hearings.
- (k) Cite a person in contempt for failure or refusal to obey the lawful order of the Board, subject to existing laws and rules.
- (l) Delegate the hearing or investigation of administrative cases filed before them whereat the hearing shall be presided over by at least one (1) member of

the Board concerned assisted by a Legal or Hearing Officer of the Commission, provided that if the charge is not related to the technical practice of the profession, the hearing may be conducted without a member of the Board.

(m) Conduct, through the Legal Officers of the Commission, summary proceedings on minor violations of the respective regulatory laws, as determined by the Board. Violations of the rules and regulations issued by the Board to implement this Act, including violations of the general instructions to examinees committed by examinees, and render summary judgment thereon which shall, unless appealed to the Commission, become final and executory after fifteen (15) days from receipt of notice of judgment or decision.

(n) Subject to the final approval by the Commission, recommend registration without examination and the issuance of corresponding certificate of registration and professional identification card to foreign pharmacists duly licensed in countries with agreement of reciprocity with the Philippine government.

(o) Prepare an annual report of accomplishments on programs, projects, and activities of the Board during the year for submission to the Commission after the close of each calendar year including appropriate recommendations on issues or problems affecting the practice of pharmacy.

(p) Issue and promulgate guidelines on continuing professional development education in coordination with the accredited professional organization.

(q) Pass resolutions that will order the closure of the program or course of pharmacy offered by a school or college.

(r) Perform other incidental and necessary acts for the effective implementation of this Act.

Section 10. *Grounds for Suspension or Termination of Term of Office of the Chairman or Member of the Board from Office.* The President of the Philippines, upon the recommendation of the Commission, after giving the Chairman or a Member of the Board an opportunity to defend himself in an administrative investigation conducted by the Commission, may remove or suspend him on any of the following grounds:

- (a) Gross neglect, incompetence or dishonesty in the discharge of duty.
- (b) Violation of any of the causes or grounds and the commission of prohibited acts provided in this Act and offenses under the Revised Penal Code, the Anti-Graft and Corruption Practices and criminal laws.
- (c) Involvement in the manipulation, tampering or rigging of the licensure examination, its questions and its results and the disclosure of classified and confidential information pertaining to the licensure examination.
- (d) Conviction of an offense involving moral turpitude by a court of

jurisdiction.

The Commission, in the conduct of investigation shall be guided by Section 7, and Section 15 of R.A. No. 8981 and the rules on administrative investigation thereof, and the applicable provisions of the New Rules of Court.

Section 11. *Passing of Licensure Examination Requirement.* Except as otherwise specifically allowed under this Act, applicants for registration for the practice of pharmacy shall be required to pass a licensure examination as provided for in this Act and in accordance with Sec. 7 (d) of R.A. No. 8981.

Section 12. *Qualifications of Applicants.* An applicant for the licensure examination for pharmacy shall satisfactorily show that he/she possesses the following qualifications:

- (a) Citizen of the Philippines or a foreign citizen whose country/state has reciprocity with the Philippines in the practice of pharmacy;
- (b) Of good moral character and reputation;
- (c) A holder of a Bachelor's degree in pharmacy duly recognized or accredited by the Commission on Higher Education (CHED) and conferred by a school/college/university duly authorized by the government or its equivalent degree obtained by either a Filipino or foreign citizen from an institution of learning in a foreign country/state, provided it is duly recognized and/or accredited by CHED;
- (d) Not convicted of an offense involving moral turpitude by a court of competent jurisdiction; and
- (e) He must have completed an Internship Program which shall consist of at least nine hundred sixty hours (960 hours), six hundred hours (600 hours) of which shall be spent equally distributed in a community pharmacy, hospital pharmacy, or pharmaceutical industry – manufacturing, regulatory, marketing, or research – and other related fields, while three hundred sixty hours (360 hours) of internship shall be spent in any of the accredited pharmacy establishments or entity chosen by the candidate.

For this purpose, the above-mentioned community pharmacy, pharmaceutical company, and hospital pharmacy shall keep a separate record of pharmacy students who underwent said internship program directly under their control and as a result thereof, shall issue the proper certificate of said hours of internship. It shall also be the duty of said establishments to submit semi-annually a complete report of the names of those who have undergone training under their supervision and the corresponding number of hours of internship credit of each of the pharmacy students to their respective colleges or schools and to the Board.

Section 13. *Scope of Examination.* The licensure examination for pharmacists shall be divided into two major divisions: Pharmacy as Science and Pharmacy as Practice. Pharmacy

as Science shall consist of subjects in Group I (Public Health, Pharmaceutical Microbiology and Parasitology), Group II (Drug Delivery Systems, Physical Pharmacy, Manufacturing Pharmacy, Quality Control I, Quality Control II), Group III (Pharmaceutical Biochemistry, Pharmacognosy, Plant Chemistry, and Philippine Medicinal Plants, Pharmacy and Chemistry of Medicinals I and Pharmacy and Chemistry of Medicinals II).

Pharmacy as Practice shall be made up of the following subjects: Group IV (Pharmaceutical Calculations, Hospital Pharmacy, Clinical Pharmacy, Dispensing and Medication Counseling), Group V (Biopharmaceutics and Pharmacokinetics, Pharmacology I, Pharmacology II, Clinical Toxicology), and Group VI (Pharmaceutical Jurisprudence and Ethics, Pharmaceutical Marketing and Entrepreneurship and Pharmaceutical Administration and Management).

The subjects shall be weighed as follows: Group I, 10%; Group II, 20%; Group III, 20%; Group IV, 20%; Group V, 20%; and Group VI, 10 %.

The Board subject to the approval by the Commission may introduce relevant changes, as the need arises, to the content of the examination and the relative weight attributed to each subject in the examination may be made after consultation with the duly recognized association of schools or colleges of pharmacy and the CHED.

Section 14. *Holding of Examination.* Examination for registration to practice pharmacy in the Philippines shall be given twice a year in such places and dates as the Commission may designate in the Resolution thereof on the Master Schedules for all licensure examinations in accordance with Sec. 7 (d) of R.A. No. 8981. The said places and dates may be subject to change under valid circumstances and reasons.

Section 15. *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 per cent (75%) or over with no ratings of fifty percent (50%) in more than two (2) subjects.

Section 16. *Registration and Licensure of Pharmacy Assistant.* A general weighted average below 75% but not lower than 70%, with no ratings of fifty percent (50%) in more than two subjects, shall qualify an examinee to be registered and licensed by the Professional Regulation Commission to practice as a pharmacy assistant who shall work under the supervision of a registered pharmacist. To be licensed as a pharmacist, a pharmacy assistant must pass succeeding board licensure examination for pharmacists with a general average rating as provided in Section 16.

Section 17. *Report of Rating.* The Board shall submit to the Commission the ratings obtained by each candidate within ten (10) calendar days after the examination, unless extended for just cause. Upon the release of the results of the examination, the Commission shall send by mail the rating received by each examinee at his/her given address using the mailing envelope submitted during the examination.

Section 18. *Oath of Profession.* All successful candidates in the licensure examination shall take their oath of profession before the Chairman or any member of the Board or any

authorized officer of the Commission to administer oaths, prior to entering the practice of pharmacy.

Section 19. *Issuance of Certificate of Registration and Professional Identification Card.* A certificate of registration shall be issued to those who are registered upon payment of fees prescribed by the Commission. It shall bear the signatures of the Chairperson and the Commissioners of the Commission and the Chairman and Members of the Board, stamped with the official seal of the Commission and of the Board, certifying the person named therein is entitled to the practice of the profession with all the privileges appurtenant thereto. Until revoked or suspended in accordance with this Act, it shall remain in full force and effect.

A professional identification card bearing the registration number and date, its validity and expiry duly signed by the Chairperson of the Commission shall likewise be issued to every registrant who has paid the prescribed fee. It shall be reissued upon compliance with the continuing professional development education requirement as specified in Article IV, Sec. 27 (d) of this Act and upon payment of the prescribed three-year registration fees therefor.

Section 20. *Affixing RPh after a Registered Pharmacist's Name.* Only pharmacists who are duly registered and licensed by the Board and the Commission has the right to affix this title, "Registered Pharmacist" or "R.Ph." after his/her name.

Section 21. *Grounds for Non-registration.* The Board shall not register any successful examinee for registration who has been:

- (a) Convicted of an offense involving moral turpitude by a court of competent jurisdiction,
- (b) Found guilty of immoral or dishonorable conduct by the Board,
- (c) Summarily adjudged guilty for violation of the General Instructions to Examinees by the Board,
- (d) Declared of unsound mind by the court of competent jurisdiction, and
- (e) Found addicted to dangerous drugs.

In refusing such registration, the Board shall give the applicant a written statement setting forth the reasons therefor and shall file a copy in its records.

Section 22. *Reissuance of Revoked Certificate of Registration, Replacement of Lost or Damaged Certificate of Registration, Professional Identification Card or Temporary/Special Permit.* The Board may upon petition, reinstate or reissue a revoked certificate of registration after two (2) years from the date of the revocation of the certificate of registration or the surrender of the revoked certificate and/or the professional identification card if still valid, to the Board and/or the Commission. The Board may or may not require the pharmacist whose certificate had been revoked to take another licensure examination. The petitioner shall prove to the Board that he/she has valid reason/s to be reinstated to the practice of pharmacy. For the grant of his/her petition, the Board shall issue a Board Resolution subject to the approval

of the Commission.

Duplicate copy of lost or damaged certificate of registration, professional identification card or temporary/special permit may be reissued in accordance with rules thereon and upon payment of the prescribed fee therefor.

Section 23. *Non-payment of the PRC Registration Fees.* The Board shall suspend a registered pharmacist from the practice of his/her profession for non-payment of the PRC registration fees for more than three (3) consecutive years from its last or previous year of payment. The resumption of his/her practice shall take place only upon payment of delinquency fees plus surcharges and interest and in accordance with the rules of the Commission. The running of the three-year period may be interrupted upon written notice about the discontinuance of his/her practice and surrender of his/her certificate of registration with professional identification card to the Board and/or the Commission.

Section 24. *Vested Rights: Automatic Registration.* All pharmacists registered before the effectivity of this Act shall automatically be registered hereunder, subject to the policy as to future requirements.

Certificates of registration and professional identification cards or temporary/special permits held by such persons in good standing at such effectivity shall have the same force and effect as though they were issued on or after the said effectivity.

Section 25. *The Accredited Integrated National Professional Organization (AINO) of Pharmacists.* The pharmacists are integrated under one national accredited professional organization that is duly registered with the Securities and Exchange Commission (SEC). The Board subject to the approval by the Commission shall accredit the said organization as the only integrated national organization for registered pharmacists (and pharmacy assistants). All pharmacists (and pharmacy assistants) whose names appear in the registry shall *ipso facto* or automatically become members thereof and shall receive all the benefits and privileges accorded to its members upon payment of the required fees and dues. Membership to the foregoing shall not be a bar to membership in any other association of pharmacists.

Section 26. *Membership to the Accredited Integrated National Professional Organization.* All registered pharmacists (and pharmacy assistants) must be members of the AINO and must maintain membership throughout the duration of the practice of the profession. Professional identification card shall not be renewed if the requirements for membership with AINO are not met including credit units for attendance to duly accredited continuing professional development (CPD) education activities.

Section 27. *Specialty Boards in Various Areas of Pharmacy Practice.* Specialty Boards created within the affiliate organizations and societies for recognition of the AINO (1) for the Board, subject to the approval of the Commissioner shall accredit specialties in various areas of practice, (2) setting standards of practice within different specialties, and (3) establishing qualifications and requirements for certification of practitioners under each specialty.

Section 28. *Scope of the Practice of Pharmacy.* A person deemed to be practicing pharmacy within the meaning of this Article is one who shall, with or without a fee, salary,

percentage or other rewards, paid or given directly to himself or indirectly through another –

- (a) Prepare, compound or manufacture, analyze, assay, preserve, store, distribute, sell and/or dispense any medicine, drug, chemicals, cosmetics, pharmaceuticals, devices or contrivances used in pursuance thereof;
- (b) render services, such as but not limited to (i) regulatory services, (ii) pharmaceutical marketing, (iii) drug information service and (iv) medication management which covers the following: drug selection and procurement, storage and distribution, dispensing, medication counseling and medication therapy monitoring, whenever the expertise and the technical knowledge of the pharmacist is required, in any drug establishment/outlet or healthcare institution or
- (c) provide other services where pharmaceutical knowledge is required; or
- (d) engage in teaching scientific, technical or professional pharmacy courses in a school or college of pharmacy; or
- (e) conduct or undertake scientific research in all aspects involving drugs and healthcare, or
- (f) dispense drugs during medical missions and in other situations where supervision of drugs is required.

All government and non-government agencies, establishments, institutions, and regulatory body with functions that involve the practice of pharmacy shall be headed and managed only by a qualified, duly registered and licensed pharmacist.

All pharmacists are expected to abide by current standards such as the Good Pharmacy Practice, Good Laboratory Practice, Good Distribution Practice, Good Manufacturing Practice, and Good Clinical Practice, which are deemed vital in the performance of one's roles and functions in different practice areas.

The Board, subject to the approval by the Commission, may add to, delete, or modify the above acts, services, or activities as the need arises.

Section 29. *Requirements for the Practice of Pharmacy.* A person can practice pharmacy in the Philippines upon compliance with the following requirements:

- (a) has satisfactorily passed the licensure examination for pharmacists given by the Board and the Commission,
- (b) is duly registered with and licensed by the Board and the Commission,
- (c) is an active member of the accredited integrated national professional organization,
- (d) has submitted continuing professional development education units as

required by the Continuing Professional Education Council for pharmacists or pertinent laws and regulations for the renewal of his/her professional identification card, and/or

- (e) a holder of a valid temporary/special permit issued by the Board and the Commission to foreign licensed pharmacists pursuant to this Act.

Section 30. *Foreign Reciprocity.* No foreigner shall be allowed to take the licensure examination for pharmacists, register, receive the certificate of registration and professional identification card, and practice pharmacy in the Philippines unless the requirements for the licensure examination and registration and practice of pharmacy imposed under the laws and the regulations in his foreign country or state are substantially the same as those required and contemplated by the Philippine laws and regulations, and unless the said foreign laws and regulations allow Filipino citizens to practice pharmacy within the territory of the said foreign state on the same basis and grant the same privileges as those enjoyed by the citizens, subjects or nationals thereof.

Section 31. *Practice through Temporary/Special Permit.* A temporary/ special permit may be issued by the Board subject to the approval of the Commission and payment of applicable fees to the following:

- (a) licensed pharmacists from foreign countries whose services whether for free or a fee
 - (1) if they are internationally renowned pharmacists or experts in any field or specialty of pharmacy,
 - (2) if their services are deemed necessary for lack of specialists or experts in a particular field,
- (b) licensed pharmacists from foreign countries or states whose services shall be for free and limited to indigent patients as beneficiaries; or
- (c) licensed pharmacists from foreign countries or states employed as visiting faculty in a field or specialty of pharmacy.

The permit shall, among other things, contain these limitations and conditions for a period of no more than one year, subject to renewal, the field or specialty of pharmacy, and the specific place of practice including clinics, hospitals, and schools of pharmacy. The Board subject to the approval by the Commission shall promulgate rules and regulations on the implementation of this particular Section.

Section 32. *Indication of Numbers: Certificate of Registration, Professional Tax Receipt and Accredited Integrated National Organization (AINO) Membership.* The pharmacist shall be required to indicate on any document he/she signs, uses or issues in connection with the practice of pharmacy the following information:

- (a) his/her registration number and date of issuance,

- (b) the expiration date of his/her professional identification card,
- (c) the Professional Tax Receipt (PTR) Number and date of issuance, and
- (d) the certificate of AINO membership (annual/lifetime), number and the official receipt of payment, number and date.

Section 33. *Registry of Pharmacists.* The Board shall prepare and maintain a registry of the names, residences and/or office addresses of all registered pharmacists which shall be updated annually in cooperation with the Accredited Integrated National Organization (AINO), indicating therein the status of the certificate of registration, professional identification card and Accredited Integrated National Organization (AINO) membership, whether valid or inactive due to death, or other reasons, delinquent, suspended or with revoked certificate of registration. The said registry of pharmacists shall be conspicuously posted within the premises of the Commission and the information therein made available to the public upon inquiry or request.

Section 34. *Display of Certificate of Registration.* It shall be the duty of every pharmacist engaged in the practice of pharmacy either on his/her own account or under the employ of another to display his/her original certificate of registration in a prominent and conspicuous place in a retail drug outlet or drug establishment which he operates or in which he/she is employed in his/her professional capacity as pharmacist. No pharmacist shall, with his/her knowledge, allow his/her certificate of registration to be displayed in such establishment when he/she is not actually employed or operating therein in his/her professional capacity.

Section 35. *Compounding and Dispensing.* No drug or 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 FDA-licensed retail drug outlet or other business establishments which are duly established in accordance with the provisions of applicable laws.

Prescription drugs and pharmacist-only over-the-counter drugs shall be dispensed only by registered pharmacists.

Prescription drugs shall be dispensed only upon presentation of a valid prescription.

Compounding and dispensing by duly registered and licensed pharmacists shall be in accordance with current good manufacturing practice, good laboratory practice, and good pharmacy practice, with the safety and protection of individual patients as ultimate objective.

Licensed pharmaceutical manufacturers, importers and wholesalers are authorized to sell their products only to duly licensed drug outlets, wholesalers and other drug establishments.

A registered and licensed pharmacist may refuse to compound, dispense or sell drugs and pharmaceutical products, if not in accordance with this Act.

Section 36. *Pharmacist Requirement and Compensation.* Every drug establishment/outlet selling prescription and pharmacist only over-the-counter drugs whether owned by the government or a private person or firm shall at all times when open for business be under the direct control, supervision, and responsibility of a registered and licensed pharmacist. For retail outlets selling only over-the-counter drugs, they shall be under the supervision of a registered and licensed pharmacist.

Processes involving the preparation, quality control, or repacking of pharmaceutical products in quantities greatly in excess of single therapeutic doses shall for each respective operation be under the direct and immediate supervision of a registered and licensed pharmacist. In the sale of pharmaceutical products, medicines and drugs, at wholesale, such business shall be conducted under the immediate supervision of a registered and licensed pharmacist.

All government and non-government agencies and units which handle the procurement and distribution of drugs should have a supervising pharmacist. All rural health units dispensing medicines should be supervised by a pharmacist or a pharmacy assistant as defined in this Act.

Pharmacists in government service shall receive a starting salary equivalent to Salary Grade 15 as provided in R.A. 6758 (Compensation and Position Classification Act of 1989) and its amendments. Those pharmacists in the private sector shall receive an entry-level salary in peso equivalent of Salary Grade 15 being received by government pharmacists.

Section 37. *Responsibility for Quality of Drugs, Cosmetics and Medical Devices.* It shall be the duty of the registered pharmacist of drug outlet/establishment to ensure that all drug products, cosmetics and medical devices conform to standards of safety, quality and efficacy and strictly adhere to the guidelines as provided for in this Act and other pertinent rules and regulations and issuances. Owners, managers, and/or pharmacists in charge of the operation of drug outlets and drug establishments shall be held responsible.

It shall be unlawful for any person to manufacture, prepare, sell or dispense any prescription drug, pharmaceutical, medical devices, or cosmetics under any fraudulent name, direction or pretense or to adulterate any drug, pharmaceutical, medical devices, or cosmetics offered for sale. Any drug, pharmaceutical product, medical device/s or cosmetics shall be held to be adulterated or deteriorated within the meaning of this section if it differs from the standard or quality or purity given in the United States Pharmacopeia/National Formulary and Philippine Pharmacopeia, in its latest edition, or any standard reference for drugs and medicines given official recognition, and those which fall within the meaning as provided for in the Food Drug, Cosmetic and Devices Act, R.A. No. 3720, as amended by pertinent laws and the Food and Drug Administration Act, R.A. 0711.

In cases of drug products sold in their original packings, 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.

Section 38. *Filling and Partial Filling of Prescription.* All prescriptions shall be filled or

compounded only by a registered and licensed pharmacist following the standards of purity, safety and quality. Completely filled prescriptions should be surrendered to the pharmacist for recording.

Partial filling of prescription is dispensing units less than the total quantity indicated in the prescription. The prescription should contain information as to how many units were served and shall be returned to the buyer after being recorded in the appropriate book or equivalent system. The drugstore, which completes the filling of the prescription, shall keep the prescription on file for a prescribed period of time.

Section 39. *Physician's sample.* Drugs, biologic products, devices or proprietary medicines, given or intended to be given for free to the physician and other qualified person by any manufacturer or distributor or its medical representative/detailman as part of its program or promotion, should not be sold.

The statement "Sample, not for sale" shall appear conspicuously on the container, package, or carton of the drug or device to be given. It shall be unlawful to remove, erase, deface already marked original labels of samples.

Section 40. *Prohibition against use of cipher or unusual terms in prescriptions and prescription switching.* Pharmacists should not compound or dispense prescriptions, recipes or formulas which are written in ciphers, codes or secret keys or prescriptions of drugs using unusual names which differ from those in standard pharmacopeias or formularies.

The pharmacist dispensing or compounding prescriptions should not substitute the drug or drugs called for in the prescription with any other drug or substance or ingredient without prior consultation with, and a written consent of the person prescribing, except in accordance with RA 6675, known as the Generics Act of 1988, and other pertinent laws and regulations.

Section 41. *Label of Dispensed Medicines.* Upon every box, bottle or package containing medicine 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, name of patient, generic name of drug; brand name, if any, strength, expiry date, directions for use, and name and address of drugstore and other requirements prescribed by the Cheaper Medicines Act (RA 9502) and its implementing rules and regulations.

Every prescription which in its preparation contains any quantity of a drug, which is habit-forming, or a derivative of such drug, shall have an auxiliary label or a notation, "Warning – May be habit forming". Such prescriptions should comply with the requirements of the R. A. 9165, the Comprehensive Dangerous Drugs Act of 2002, and any future amendments thereto.

Filled prescription for external use shall bear the auxiliary label, "For External Use".

Section 42. *Record Books for Prescription.* All prescriptions dispensed in the drugstore shall be recorded in the book or an equivalent recording system approved by FDA for this purpose indicating therein, among others, the prescription number, name of prescriber, generic name and brand, dosage strength, quantity of drug, name of the patient and address,

and initials of pharmacist. It shall be open to inspection by the proper authorities at any time of the day when the pharmacy is open to the public and must be preserved for a period of not less than two (2) years after the last entry in it has been made.

All prescriptions shall be attached to the prescription book or compiled (for equivalent recording system) and numbered consecutively and shall be preserved for the same period of time as required.

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 R.A. 9165.

Section 43. *Requirements for the Opening and Operation of Retail Drug Outlet or Establishment.* The minimum requirements necessary for the opening of retail drug outlet or establishment shall be in accordance with the rules and regulations prescribed by the Food and Drug Administration in accordance with the provisions of this Act.

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

Section 44. *Handling of Drugs by Persons Other than a Pharmacist.* Persons handling drugs other than the pharmacist are: professional medical representatives, pharmacy assistants, pharmacy aides/clerks, and other persons who assist pharmacists in dispensing medicines or any other person performing functions involving the handling of drugs and drug products. It is preferred that these positions are occupied by those who finished pharmacy degree, not necessarily licensed as pharmacists and who has undergone the prescribed training from a Board-accredited provider.

The professional medical representative one who represents any duly authorized manufacturer, distributor, trader and wholesaler of drugs, pharmaceuticals, biologic products and devices, whose primary duty is to introduce said products to legitimate prescribers and which forms part of their program for promotion by describing its use, composition, action, dosage, administration, contraindication, advantages and other relevant information about the drugs being promoted.

The pharmacy assistant is one who helps the pharmacist in compounding, dispensing of medicines and giving of information on proper use of medicines while the pharmacy aide/clerk is involved in other aspects of operation assigned by the pharmacist.

Any person who shall be employed or engaged as professional medical representative or pharmacy aide/clerk shall undergo comprehensive standardized training programs approved by the Board with providers approved and/or accredited by the Board in accordance with criteria established therefor.

Section 45. *Revocation or Suspension of the Certificate of Registration and*

Cancellation of Temporary or Special Permit. The Board shall have the power, upon notice and hearing to revoke or suspend the certificate of registration of a registered pharmacist or to cancel a temporary or special permit granted to a foreign pharmacist on the basis of the following:

- (a) Violation of this Act on unauthorized practice of pharmacy, violation of any provision of this Act, the Rules and Regulations (RR) thereof, the Code of Ethics for Pharmacists, Code of Good Governance, Code of Technical Standards for the practice of pharmacy, policy, and measure of the Board and/or the Commission;
- (b) Malpractice or gross incompetence; negligence, or imprudence resulting to death or injury of the patient;
- (c) Dishonorable conduct and/or conviction by a competent court of any criminal offense involving moral turpitude;
- (d) Fraud or deceit in the acquisition of the certificate of registration, professional identification card or temporary/special permit or renewal of license;
- (e) Display of certificate of registration of a pharmacist who is not actually employed in such an establishment as required by law.
- (f) Addiction to alcoholic beverages or to any habit-forming drug rendering him incompetent to practice his/her profession;
- (g) Aiding or abetting the illegal practice of a non-registered and licensed person by allowing him/her the use of his/her certificate of registration and/or professional identification card or his/her special/temporary permit;
- (h) Acting as a dummy of an alien or a person who is not qualified to establish and operate a retail drugstore;
- (i) Insanity or any mental disorder that would render the person incompetent to practice his/her profession;
- (j) False, extravagant or unethical advertisements and product endorsements where the pharmacist's name, professional organization he/she represents, and similar information are used;
- (k) Manufacture, sale, offering for sale of counterfeit drugs and committing other acts in violation of Sec. 4 of the Special Law on Counterfeit Drugs, R.A. No. 8203;
- (l) Illegal manufacturing, sale, possession, dispensing of dangerous drugs and other pertinent acts in violation of Dangerous Drugs Act, R.A. No.

9165;

- (m) Committing acts in violation of Sec. 6 of P.D. No. 881 on Hazardous Substances; and
- (n) Practicing pharmacy while under suspension.
- (o) Practicing with an expired professional identification card.

Section 46. *Non-renewal of license.* The following are the grounds for the non-renewal of professional identification card:

- (a) Refusal to join or to remain a member of good standing of the AINO;
- (b) Non-payment of annual registration fees for three (3) continuous years;
- (c) Non-compliance with the continuing professional development requirement, for the renewal of his/her professional identification card; and

The Board shall periodically evaluate the aforementioned grounds and revise as the need arises subject to the approval of the Commission.

Any person, entity or organization may file charges according to the provision of this section against any registrant, or the Board may investigate violation of any of the abovementioned causes. Affidavit of complaint under oath shall be filed together with the affidavits of witnesses and other documentary evidence with the Board through the Legal and Investigation Office. The move to conduct an investigation shall be embodied in a formal charge to be signed by at least a majority of the members of the Board. The rules on administrative investigation issued by the Commission shall govern the hearing or investigation subject to applicable provisions of this Act, R.A. No. 8981 and its rules and regulations thereof, and Rules of Court.

Section 48. *Administrative Investigation and Sanctions.* Administrative investigations shall be conducted by the Board assisted by the Legal or Hearing Officer of the Commission. The existing rules of evidence shall also be observed and applied during administrative investigations.

If the Board, by a majority vote of the members, shall find that the charges are sustained by evidence adduced, it may, at its discretion reprimand the respondent or revoke or suspend his certificate of registration.

Section 49. *Procedure and Rules in Administrative Investigation.* The Board upon receipt of a formal complaint under oath against any pharmacist shall furnish the latter a copy of the complaint, which shall be answered in writing within ten (10) days from receipt thereof. If the Board, after careful study of the records, finds that there is a valid ground to the charge, it shall conduct a formal investigation and set the dates of the hearing thereof.

For this purpose, subpoenas may be issued by the chairman of the Board or by the Chief, Legal and Investigation Division. The investigation proceedings shall at all times be recorded. The investigation shall have been terminated and resolved within ninety (90) days from the time the first date of hearing shall be set and heard.

The respondent pharmacist is entitled to be heard or be represented by counsel; to have speedy public hearing, to confront, and to cross-examine the witness or witnesses against him; to summon and present witness or witnesses in his behalf; or to avail himself of any other process for the protection of his/her constitutional rights.

An appeal and a motion for reconsideration may be filed within ten (10) days from receipt of a resolution on the existence of the following grounds: (1) grave abuse of discretion by the Board; (2) findings not supported by substantial evidence; and (3) irregularity in the conduct of investigation.

Section 50. *Appeal/Finality of Decision.* The decision of the Board shall automatically become final and executory after the lapse of fifteen (15) days from the receipt of the resolution of a respondent, unless the latter has made an appeal or a motion for reconsideration. The resolution of the Board may be appealed to the Commission and the decision of the Commission may then be appealed to the Office of the President.

Section 51. *Penal Provisions.* Any person who shall violate any of the provisions of the practice of pharmacy, as defined in this Act, shall be punished according to the following rules:

(a) The following acts shall be punishable by a fine not less than Fifty Thousand Pesos (P 50,000.00) but not exceeding One Hundred Thousand Pesos (P 100,000.00) and be imprisoned for a period not less than three (3) months but not more than six (6) months:

- i. Affixing of the title, R.Ph. by a person who is not a pharmacist and a graduate of pharmacy degree who is not registered with PRC (Section 21)
- ii. Practice of pharmacy in the Philippines by a foreigner without special permit (Section 28)
- iii. Non-indication by a pharmacist of his/her registration number and Professional Tax Receipt number in official documents requiring such information (Section 30)
- iv. Non-display of certificate of registration of a pharmacist in drug establishment requiring such (Section 32)
- v. Non-display of certificate of registration of a pharmacist by an establishment/outlet (Section 32)
- vi. Non-compliance with this Act's provision on the required salary for a registered pharmacist (Section 34)

- vii. Non-compliance by a pharmacist with the requirement on the filling of prescription (Section 36)
- viii. Non-compliance by a registered pharmacist on the requirement for partially filled prescription (Section 36)
- ix. Selling of physician's samples (Section 37)
- x. The removal, erasure and alteration of mark or label of physician's sample (Section 37)
- xi. Non-compliance with the filling up of Record Books by a drug outlet (Section 40)
- xii. Employment of persons in a pharmacy without the provision of the required training (Section 42)
- xiii. Rendering dispensing-related services by non-pharmacists in a drug outlet without undergoing the required training

(b) The following acts shall be punishable by a fine not less than One Hundred Thousand Pesos (P 100,000.00) but not exceeding Two Hundred Fifty Thousand Pesos (P 250,000.00) and be imprisoned for a period not less than six (6) months but not more than one (1) year:

- i. Allowing the display of his/her registration certificate in an outlet or establishment by a pharmacist where he/she is not employed
- ii. Display of a pharmacist's registration certificate by an outlet or establishment when the pharmacist is not employed
- iii. Dispensing done in, or offering for sale of prescription drugs in a place not licensed by FDA as drug outlet
- iv. Dispensing of prescription of and pharmacist-only over-the-counter drugs by a person other than a registered pharmacist
- v. Dispensing of prescription drugs without presentation of a valid prescription
- vi. Compounding of prescription drugs and pharmacist-only over-the-counter drugs done by a person other than a pharmacist
- vii. Selling of prescription and pharmacist-only over-the-counter drugs by manufacturers, importers, and wholesalers to unlicensed drug outlets and other drug establishments
- viii. Substitution of prescription drugs which are not generically equivalent to what was on the prescription without the consent of the prescriber

- ix. Compounding not in accordance with the current Good Manufacturing Practices and Good Pharmacy Practice
- x. Forcing, coercing or intimidating a registered pharmacist to compound or dispense drugs not in accordance with this Act
- xi. Preparation and compounding of pharmaceutical products in quantities greatly in excess of single therapeutic doses without a registered pharmacist
- xii. Non-compliance with the labeling requirement for dispensed medicines by a drug outlet
- xiii. Allowing pharmacy assistants to dispense without the supervision of a pharmacist.
- xiv. Establishment/outlet selling prescription and pharmacist-only over-the-counter drugs which opens for business without a licensed pharmacist.
- xv. Compounding by a non-registered pharmacist or pharmacist with expired/revoked/suspended license.
- xvi. Filling of prescription by a non-pharmacist or by a non-registered pharmacist or pharmacist with expired/revoked/suspended license.
- xvii. Wholesale of pharmaceutical products without the direct and immediate supervision of a registered pharmacist.
- xviii. Rural Health Units dispensing prescription drugs and pharmacist-only over-the-counter drugs without the supervision of a registered pharmacist.

(b) The following shall be the acts punishable by a fine of not less than Two Hundred Fifty Thousand (P 250,000.00) Pesos but not exceeding Five Hundred Thousand (P 500,000.00) Pesos and be imprisoned for a period not less than one year and one day but not more than six years. The following shall be the acts punishable under this Section:

- i. Manufacturing and selling of pharmaceutical products under fraudulent name and address (Section 35)
- ii. Adulteration and misbranding of drugs (Section 35)
- iii. Manufacturing and selling of unsafe and substandard drugs

Any person, who is not a citizen of the Philippines, who shall be found guilty of any violation as provided for in this Section shall, after having paid the fine or having served his sentence, be also subject to immediate deportation.

Section 52. *Implementing Rules and Regulations.* The Board, in consultation with the Commission, Office of the President, Department of Health, and Civil Service Commission shall issue the necessary implementing rules and regulations within sixty (60) days after the effectivity of this Act.

Section 53. *Appropriations.* The Commission shall immediately include in its programs on 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.

Section 54. *Repealing Clause.* - All laws, presidential decrees, executive orders, and rules and regulations, or parts thereof, inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

Section 55. *Separability Clause.* - If, for any reason, any section or provision of this Act is held unconstitutional or invalid, the other sections or provisions hereof shall not be affected hereby.

Section 56. *Effectivity Clause.* - This Act shall take effect after its complete publication in at least two (2) national newspapers of general circulation.

APPROVED,