

RECEIVED BY

SIXTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session

13 JUL 10 A9:14

SENATE

)

)

)

S. B. No. 698

Introduced by Senator FRANCIS G. ESCUDERO

EXPLANATORY NOTE

This bill proposes to professionalize the practice of pharmacy by setting a national standard for the profession, likewise creating a professional regulatory board to ensure excellent, globally competitive, and accountable practice of the same.

Pharmacy as a health profession links the health sciences with the chemical sciences and is charged with ensuring the safe and effective use of pharmaceutical drugs. The scope of the pharmacy practice involves traditional roles such as compounding and dispensing medications, but also includes more modern services related to health care, including clinical services, reviewing medications for safety and efficacy, and providing drug information. Pharmacists, therefore, are and should be experts on drug therapy, and are the primary health professionals who optimize the use of medication to provide patients with positive health outcomes. Education and experience in the field should therefore be underscored.

This bill seeks to address the competency needs of the profession and also curb both unintentional or intentional harm that may be caused by an unregulated practice. This proposed measure will fulfill this objective through the:

- 1. Definition of the scope of nature and regulations of the professional practice of pharmacy;
- 2. Creation of the Professional Regulatory Board of Pharmacy;
- 3. Setting up of criteria or qualifications for the licensure of practitioners; and
- 4. Imposition of penalties for violators of this Act.

In view of the foregoing, the passage of this bill is earnestly sought.

FRANCIS G. ESCUDERO

SIXTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES First Regular Session

1

2



\$ 20

'13 JUL 10 A9:14

SENATE

)

)

S. B. No. 698

RECEIVED BY:

Introduced by Senator FRANCIS G. ESCUDERO

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 of the Republic of the Philippines in Congress assembled:

ARTICLE I

GENERAL PROVISIONS

3 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 quality healthcare delivery through their services in providing safe, effective, and quality drugs or medicines; drug information, patient medication counseling, and health promotion. The pharmacists' professional service shall, therefore, be promoted as a component of the total healthcare system, which shall ensure the physical wellbeing 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, qualitative, world-class and internationally recognized, globally competitive through regulatory measures, programs, and activities that foster their continuing professional development.

- 15 Sec. 3. *Objectives.* This Act provides for, and shall govern:
- 16 (a) the standardization and regulation of pharmacy education,
- 17 (b) the examination for registration of graduates of schools and colleges of 18 pharmacy,
- 19 (c) the supervision, control, and regulation of the practice of pharmacy in the 20 Philippines
- (d) the enhancement of professional competence through continuing professional
 development, research, and other related activities and
- 23 (e) the integration of the pharmacy profession.
- 24 Sec. 4. *Definition of Terms.* For purposes of this Act, the term:

(a) *Biologic Products* are microorganisms, sera, toxins and similar products used for the prevention or cure of human diseases.

1

2

3

4

5

6

7

8

9

- (b) *Brand Name* means the proprietary or trade name given by the manufacturer to distinguish its product from those of the competitors.
- (c) *Cipher* means 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 means a system of words or other symbols arbitrarily used to represent words.
- 10 (e) *Compounding* is the preparation, mixing, assembling, packaging, or labeling of a 11 drug (i) as the result of a prescription or drug order by a physician, dentist, 12 optometrist, or veterinarian, based on the said practitioner-patient-pharmacist 13 relationship in the course of professional practice, or (ii) for the purpose of, or in 14 relation to, research, teaching, or chemical analysis and not for sale or 15 dispensing.
- 16 (f) *Cosmetics* are (i) products intended to be applied, poured, sprinkled, or sprayed 17 on, introduced into, or otherwise applied to the human body, or any part thereof 18 for cleansing, beautifying, promoting attractiveness or improving the 19 appearance, or (ii) ingredients or other substances intended for use as a 20 component of any such product.
- (g) Counterfeit drug/medicine/pharmaceutical refers 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;
- 34 (ii) a drug product refilled in containers by unauthorized persons if the
 35 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 or
 efficacy due to expiration.

1 2 3 4 5	Conv Sched enum	erous drugs include those listed in the Schedules annexed to the 1961 Single ention on Narcotic Drugs as amended by the 197 Protocol, and in the lules annexed to the 1971 Single Convention on Psychotropic Substances as herated in the attached annex in Republic Act No. 9165, which is an integral of the Act.
6 7	• •	es refers to any instrument, apparatus, implement, machine, implant, in reagent or calibrator, software, material or other similar or related article:
8 9	• •	tended by the manufacturer to be used, along or in combination, for n beings for one or more of the specific purpose(s) of:
10	(i) diagnosis, prevention, monitoring, treatment, alleviation of diseases	
11	of diseases,	
12 13	(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury	
14 15	(iii) investigation, replacement or modification or support of the anatomy of a physiological process,	
16	(iv) su	pporting or sustaining life,
17	(v) c	control of conception,
18	(vi) c	lisinfection of medical devices,
19 20		providing information for medical or diagnostic purposes by means of an in vitro examination of specimen derived from the human body; and
21 22 23	by pl	hich does not achieve its primary intended action in or on the human body narmacological, immunological or metabolic means, but which may be ed in their intended function by such means.
24 25 26	(j) <i>Dispensing</i> is 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.	
27 28 29	(k) <i>Drugs and Medicines</i> refer 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 but not limited to:	
30 31 32 33 34 35	(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;
36 37	(ii)	any article intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease of man and animals;
38 39	(iii)	any article other than food intended to affect the structure or any function of the human body or animals;

,

,

د ۲

.

, 1

(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

1

2

3

4

5

6

7

8

9

10 11

20

21

22 23

24

25

26

27

- (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).
- 12 (1) Drug or Pharmaceutical Laboratory or Pharmaceutical Manufacturing Laboratory
 13 means an establishment where pharmaceutical products, proprietary medicines,
 14 or pharmaceutical specialties are formulated, prepared, compounded, and
 15 standardized.
- 16 (m)*Drug Establishments* means FDA-registered companies involved in the 17 manufacture, importation, repacking, and/or distribution of drugs or medicines.
- (n) Drug Outlets refer to drugstores, pharmacies, and other business establishments
 which are registered with the FDA and which legally sell drugs and medicines.
 - (o) *Drugstore* or *Pharmacy* means 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* means 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 refers to the act of dispensing or giving out of medicines in accordance with the doctor's order.
- (r) Household Remedies shall refer to 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 means the scientifically and internationally recognized name of the
 active ingredient/s as approved by the Food and Drug Administration.
- (t) Label means a display of written, printed or graphic information upon the
 immediate container, or attached to or accompanying any pharmaceutical
 products.
- (u) Labeling means 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 are drugs used for symptomatic relief of minor ailments
 which may be dispensed without a prescription.

- (w) *Pharmaceutical products or Pharmaceutical specialties* are 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.
- 4 (x) *Pharmacist-only over-the-counter drugs* are FDA-classified over-the-counter drugs 5 and/or substances which should only be obtained from the drugstore or 6 pharmacy with mandatory pharmacist's advice on their selection and proper 7 use.
- 8 (y) *Person* includes an individual, partnership, corporation, or any juridical entity.
- 9 (z) *Pharmaceutical marketing* means any activity undertaken, organized or sponsored 10 by a drug establishment which is directed at promoting the prescription, 11 recommendation, supply, administration or consumption of its pharmaceutical 12 product(s) through direct personal contact and all media, including the internet.
- (aa) *Pharmacy Assistants* are those 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.
- 17 (bb) *Physician's samples* refer to medicines given to a physician for free for 18 promotional purposes.
- (cc) Prescription drugs are those 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 refers to the 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 means a characteristic style or symbols kept from the knowledge of
 others or disclosed confidentially to a few individuals.

Sec. 5. - Enforcement. - The Professional Regulatory Board of Pharmacy and the
 Professional Regulation Commission are the body responsible for the implementation
 of the provisions of this Act.

31 32

1

2

3

ARTICLE II

THE PROFESSIONAL REGULATORY BOARD OF PHARMACY

Sec. 6. - The Board of Pharmacy and its Composition. - There is hereby created a 33 Professional Regulatory Board of Pharmacy, hereinafter called the Board, under the 34 administration, control, and supervision of the Professional Regulation Commission 35 therein after called the Commission, composed of a Chairman and four (4) members, 36 each of which represent the areas of practice of community, hospital, manufacturing, 37 academe, and government service, who shall be appointed by the President of the 38 Philippines from the recommendees ranked by the Commission from the list of .39 nominees submitted by the Accredited Integrated National Organization for 40 Pharmacists. 41

Sec. 7. - Qualifications of Board Members. - To be appointed as member of the Board
 of Pharmacy, a person shall be:

- 3 (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;
- (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; and
- (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.

17 Sec. 8. – *Term of Office of Board Members.* – The chairman and the members of the 18 Board shall hold office for three (3) years after appointment or until their successors 19 shall have been appointed and duly qualified; Provided, the incumbent Board members 20 shall finish their terms to complete the membership of the Board. *Provided*, further, that 21 the chairman or any member may be re-appointed for another term but in no case shall 22 he/she serve for more than six years.

Sec. 9. – *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 the Commissioner, 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 shall be entitled to other allowances and benefits provided under existing laws.

- Sec. 10. Powers, Functions and Duties of the Board. The Board shall exercise these
 specific powers, functions, and duties:
- 32 (a) Conduct licensure examination for pharmacists;
- (b) Approve the registration of pharmacists and the certification of drug handlers as
 covered by Sec. 42 of this Act;
- (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 cause/s;
- 42 (d) Review and/or amend the scope of licensure examination;
 - 6

(e) Add, delete, modify the scope, definition and standards of practice of pharmacy;

1

2

3

4

5

- (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/or 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 16 promulgated thereunder and the Pharmacist's Code of Ethics, technical 17 standards, and other Board issuances and for this purpose, may issue summons, 18 19 subpoena duces ad testificandum and subpoena duces tecum to the respondents and/or witnesses to compel their attendance in such investigations or hearings: 20 Provided that, the decision of the Board shall, unless appealed to the Commission, 21 becomes final and executory after fifteen (15) days from receipt of notice of 22 judgment or decision; 23
- (k) Cite a person in contempt for failure or refusal to obey the lawful order of the
 Board in accordance with the Revised Rule of Court;
- (1) 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;
- 42 (o) Prepare an annual report of accomplishments on programs, projects, and 43 activities of the Board during the year for submission to the Commission after
 - 7

1 2

3

4

5

6

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) Recommend to the CHED for the closure of the program or course of pharmacy offered by a school/college pursuant to the latter's policy thereon; and
- 7 (r) Perform any implied, incidental, necessary power for the effective
 8 implementation of this Act.

9 Sec. 11. – Grounds for Suspension or Termination of Term of Office of the Chairman or 10 Member of the Board from his/her Office. - The President of the Philippines, upon the 11 recommendation of the Commission, after giving the Chairman or the member of the 12 Board an opportunity to defend himself/herself in an administrative investigation 13 conducted by the Commission, may remove or suspend him/her on any of the 14 following grounds:

- 15 (a) Gross neglect, incompetence or dishonesty in the discharge of his/her duty;
- (b) Violation of any of the causes/grounds/ and the prohibited acts provided in
 this Act and the offenses in the Revised Penal Code, the Anti-Graft and
 Corruption Practices and other laws;
- (c) Involvement in the manipulation, tampering or rigging of the licensure
 examination, its questions and/or its results and the disclosure of classified and
 confidential information pertaining to the licensure examination.
- 22 (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.

26 ARTICLE III
 27 EXAMINATION, REGISTRATION, CERTIFICATION, AND LICENSURE

Sec. 12. - *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.

Sec. 13. - 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;
- 36 (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;

4 (d) Not convicted of an offense involving moral turpitude by a court of competent
 5 jurisdiction; and

1

2

3

(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 abovementioned community pharmacy, pharmaceutical 13 company, and hospital pharmacy shall keep a separate record of pharmacy students 14 who underwent said internship program directly under their control and as a result 15 thereof, shall issue the proper certificate of said hours of internship. It shall also be 16 the duty of said establishments to submit semi-annually a complete report of the 17 names of those who have undergone training under their supervision and the 18 corresponding number of hours of internship credit of each of the pharmacy 19 students to their respective colleges or schools and to the Board. 20

Sec. 14. - Scope of Examination. - The licensure examination for pharmacists shall be 21 divided into two major divisions: Pharmacy as Science and Pharmacy as Practice. 22 Pharmacy as Science shall consist of subjects in Group I (Public Health, Pharmaceutical 23 Microbiology and Parasitology), Group II (Drug Delivery Systems, Physical Pharmacy, 24 Manufacturing Pharmacy, Quality Control I, Quality Control II), Group III 25 (Pharmaceutical Biochemistry, Pharmacognosy, Plant Chemistry, and Philippine 26 Medicinal Plants, Pharmacy and Chemistry of Medicinals I and Pharmacy and 27 28 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 %.

37 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.

41 Sec. 15. - Holding of Examination. - Examination for registration to practice pharmacy 42 in the Philippines shall be given twice a year in such places and dates as the 43 Commission may designate in the Resolution thereof on the Master Schedules for all 44 licensure examinations in accordance with Sec. 7 (d) of R.A. No. 8981. The said places 45 and dates may be subject to change under valid circumstances and reasons. Sec. 16. – 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.

Sec. 17. <u>Registration and Licensure</u> 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.

Sec. 18. - 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.

Sec. 19. – 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.

Sec. 20. - Issuance of Certificate of Registration and Professional Identification Card. -20 A certificate of registration shall be issued to those who are registered upon payment of 21 fees prescribed by the Commission. It shall bear the signatures of the Chairperson and 22 the Commissioners of the Commission and the Chairman and Members of the Board, 23 stamped with the official seal of the Commission and of the Board, certifying the person 24 named therein is entitled to the practice of the profession with all the privileges 25 appurtenant thereto. Until revoked or suspended in accordance with this Act, it shall 26 remain in full force and effect. 27

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 threeyear registration fees therefor.

Sec. 21. - 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.

37 Sec. 22. - Grounds for Non-registration. - The Board shall not register any successful
 38 examinee for registration who has been:

- 39 (a) Convicted of an offense involving moral turpitude by a court of competent
 40 jurisdiction,
- 41 (b) Found guilty of immoral or dishonorable conduct by the Board,
- 42 (c) Summarily adjudged guilty for violation of the General Instructions to
 43 Examinees by the Board,

(d) Declared of unsound mind by the court of competent jurisdiction, and

(e) Found addicted to dangerous drugs.

1

2

34 35

In refusing such registration, the Board shall give the applicant a written statement 3 setting forth the reasons therefor and shall file a copy in its records. 4

Sec. 23. - Reissuance of Revoked Certificate of Registration, Replacement of Lost or 5 Damaged Certificate of Registration, Professional Identification Card 6 or Temporary/Special Permit. - The Board may upon petition, reinstate or reissue a 7 revoked certificate of registration after two (2) years from the date of the revocation of 8 the certificate of registration or the surrender of the revoked certificate and/or the 9 professional identification card if still valid, to the Board and/or the Commission. The 10 Board may or may not require the pharmacist whose certificate had been revoked to 11 take another licensure examination. The petitioner shall prove to the Board that he/she 12 has valid reason/s to be reinstated to the practice of pharmacy. For the grant of his/her 13 petition, the Board shall issue a Board Resolution subject to the approval of the 14 Commission. 15

16 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 17

upon payment of the prescribed fee therefor. 18

19 Sec. 24. - 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 20 PRC registration fees for more than three (3) consecutive years from its last or previous 21 year of payment. The resumption of his/her practice shall take place only upon 22 payment of delinquency fees plus surcharges and interest and in accordance with the 23 rules of the Commission. The running of the three-year period may be interrupted upon 24 written notice about the discontinuance of his/her practice and surrender of his/her 25 certificate of registration with professional identification card to the Board and/or the 26 Commission. 27

Sec. 25. - Vested Rights: Automatic Registration. - All pharmacists registered before 28 the effectivity of this Act shall automatically be registered hereunder, subject to the 29 policy as to future requirements. 30

Certificates of registration and professional identification cards or temporary/special 31 permits held by such persons in good standing at such effectivity shall have the same 32 force and effect as though they were issued on or after the said effectivity. 33

ARTICLE IV

REGULATION OF THE PRACTICE OF PHARMACY

Sec. 26. - Scope of the Practice of Pharmacy. - A person deemed to be practicing 36 pharmacy within the meaning of this Article is one who shall, with or without a fee, 37 salary, percentage or other rewards, paid or given directly to himself or indirectly 38 through another -39

(a) Prepare, compound or manufacture, analyze, assay, preserve, store, distribute, 40 sell and/or dispense any medicine, drug, chemicals, cosmetics, pharmaceuticals, **4**1 devices or contrivances used in pursuance thereof; or 42

- (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
- 8 (c) provide other services where pharmaceutical knowledge is required; or
- 9 (d) engage in teaching scientific, technical or professional pharmacy courses in a
 10 school or college of pharmacy; or
- 11 (e) conduct or undertake scientific research in all aspects involving drugs and 12 healthcare, or
- 13 (f) dispense drugs during medical missions and in other situations where 14 supervision of drugs is required.

15 All government and non-government agencies, establishments, institutions, and 16 regulatory body with functions that involve the practice of pharmacy shall be headed 17 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

21 roles and functions in different practice areas.

1

2

3

4

5

6

7

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.

Sec. 27. – Prerequisites for the Practice of Pharmacy. – A person can practice pharmacy
 in the Philippines provided he/she:

- (a) has satisfactorily passed the licensure examination for pharmacists given by the
 Board and the Commission,
- 28 (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.

37 Sec. 28. – Foreign Reciprocity. – No foreigner shall be allowed to take the licensure 38 examination for pharmacists, register, receive his/her certificate of registration and 39 professional identification card, and practice pharmacy in the Philippines unless the 40 requirements for the licensure examination and registration and practice of pharmacy imposed under the laws and the regulations in his/her 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 country/state on the same basis and grant the same privileges as those enjoyed by the citizens, subjects or nationals thereof.

Sec. 29. - 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
- 12 (1) if they are internationally renowned pharmacists or experts in any field or13 specialty of pharmacy,
- 14 (2) if their services are deemed necessary for lack of specialists or experts in a15 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.

Sec. 30. – 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:

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

Sec. 31. – 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.

3 Sec. 32. - Display of Certificate of Registration. - It shall be the duty of every 4 pharmacist engaged in the practice of pharmacy either on his/her own account or 5 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 6 operates or in which he/she is employed in his/her professional capacity as 7 pharmacist. No pharmacist shall, with his/her knowledge, allow his/her certificate of 8 registration to be displayed in such establishment when he/she is not actually 9 employed or operating therein in his/her professional capacity. 10

11 Sec. 33. – Compounding and Dispensing. – No drug or pharmaceutical product of 12 whatever nature and kind shall be compounded, dispensed, sold or resold, or otherwise 13 be made available to the consuming public except through a FDA-licensed retail drug 14 outlet or other business establishments which are duly established in accordance with 15 the provisions of applicable laws.

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

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

19 Compounding and dispensing by duly registered and licensed pharmacists shall be in

20 accordance with current good manufacturing practice, good laboratory practice, and

21 good pharmacy practice, with the safety and protection of individual patients as

22 ultimate objective.

23 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.

28 Sec. 34. -Pharmacist Requirement and Compensation. - Every drug establishment/outlet selling prescription and pharmacist only over-the-counter drugs 29 whether owned by the government or a private person or firm shall at all times when 30 open for business be under the direct control, supervision, and responsibility of a 31 registered and licensed pharmacist. For retails outlets selling only over-the-counter 32 drugs, they shall be under the supervision of a registered and licensed pharmacist. 33

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

42 dispensing medicines should be supervised by a pharmacist or a pharmacy assistant as

43 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.

6 Sec. 35. – Responsibility for Quality of Drugs, Cosmetics and Medical Devices. – It 7 shall be the duty of the registered pharmacist of drug outlet/establishment to ensure 8 that all drug products, cosmetics and medical devices conform to standards of safety, 9 quality and efficacy and strictly adhere to the guidelines as provided for in this Act and 10 other pertinent rules and regulations and issuances. Owners, managers, and/or 11 pharmacists in charge of the operation of drug outlets and drug establishments shall be 12 held responsible.

It shall be unlawful for any person to manufacture, prepare, sell or dispense any 13 prescription drug, pharmaceutical, medical devices, or cosmetics under any fraudulent 14 name, direction or pretense or to adulterate any drug, pharmaceutical, medical devices, 15 or cosmetics offered for sale. Any drug, pharmaceutical product, medical device/s or 16 cosmetics shall be held to be adulterated or deteriorated within the meaning of this 17 18 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, 19 or any standard reference for drugs and medicines given official recognition, and those 20 which fall within the meaning as provided for in the Food Drug, Cosmetic and Devices 21 Act, R.A. No. 3720, as amended by pertinent laws and the Food and Drug 22 Administration Act, R.A. 0711. 23

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.

Sec. 36. - 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.

Sec. 37. - *Physician's sample.* - Drugs, biologic products, devices or proprietary
 medicines, given or intended to be given 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.

44 Sec. 38. – Prohibition against use of cipher or unusual terms in prescriptions and 45 prescription switching – Pharmacists should not compound or dispense prescriptions, 1 recipes or formulas which are written in ciphers, codes or secret keys or prescriptions of

2 drugs using unusual names which differ from those in standard pharmacopeias or 3 formularies.

4 The pharmacist dispensing or compounding prescriptions should not substitute the 5 drug or drugs called for in the prescription with any other drug or substance or 6 ingredient without prior consultation with, and a written consent of the person 7 prescribing, except in accordance with RA 6675, known as the Generics Act of 1988, and 8 other pertinent laws and regulations.

9 Sec. 39. - Label of Dispensed Medicines. - Upon every box, bottle or package containing 10 medicine compounded or dispensed by a registered and licensed pharmacist based on 11 prescription, there shall be pasted, affixed or imprinted a seal or label bearing, among 12 others, name of patient, generic name of drug; brand name, if any, strength, expiry date, 13 directions for use, and name and address of drugstore and other requirements 14 prescribed by the Cheaper Medicines Act (RA 9502) and its implementing rules and 15 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.

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

Sec. 40. - Record Books for Prescription. - All prescriptions dispensed in the drugstore 22 shall be recorded in the book or an equivalent recording system approved by FDA for 23 this purpose indicating therein, among others, the prescription number, name of 24 prescriber, generic name and brand, dosage strength, quantity of drug, name of the 25 patient and address, and initials of pharmacist. It shall be open to inspection by the 26 proper authorities at any time of the day when the pharmacy is open to the public and 27 must be preserved for a period of not less than two (2) years after the last entry in it has 28 been made. 29

30 All prescriptions shall be attached to the prescription book or compiled (for equivalent

31 recording system) and numbered consecutively and shall be preserved for the same

32 period of time as required.

33 All required information on dangerous drugs dispensed by a pharmacy shall be

recorded in the Dangerous Drugs book or an equivalent recording system as requiredby R.A. 9165.

Sec. 41. - 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.

Sec. 42. - Handling of Drugs by Persons Other than a Pharmacist. - For the purpose of 1 this section, persons handling drugs other than the pharmacist are: professional medical 2 representatives, pharmacy assistants, pharmacy aides/clerks, and other persons who 3 assist pharmacists in dispensing medicines or any other person performing functions 4 involving the handling of drugs and drug products. It is preferred that these positions 5 are occupied by those who finished pharmacy degree, not necessarily licensed as 6 pharmacists and who has undergone the prescribed training from a Commission-7 accredited provider. 8

9 The professional medical representative or detailman is one who represents any duly 10 authorized manufacturer, distributor, trader and wholesaler of drugs, pharmaceuticals, 11 biologic products and devices, whose primary duty is to introduce said products to 12 legitimate prescribers and which forms part of their program for promotion by 13 describing its use, composition, action, dosage, administration, contraindication, 14 advantages and other relevant information about the drugs being promoted.

15 The pharmacy assistant is one who helps the pharmacist in compounding, dispensing 16 of medicines and giving of information on proper use of medicines while the pharmacy

17 aide/clerk is involved in other aspects of operation assigned by the pharmacist.

18 Any person who shall be employed or engaged as professional medical representative 19 or pharmacy aide/clerk shall undergo comprehensive standardized training programs 20 approved by the Board with providers approved and/or accredited by the Board in

21 accordance with criteria established therefor.

22

24

ARTICLE V

23 ACCREDITED INTEGRATED NATIONAL ORGANIZATION FOR PHARMACISTS

Sec. 43. - The Accredited Integrated National Professional Organization (AINO) of 25 Pharmacists - The pharmacists are integrated under one national accredited 26 professional organization that is duly registered with the Securities and Exchange 27 Commission (SEC). The Board subject to the approval by the Commission shall accredit 28 the said organization as the only integrated national organization for registered 29 pharmacists (and pharmacy assistants). All pharmacists (and pharmacy assistants) 30 whose names appear in the registry shall ipso facto or automatically become members 31 thereof and shall receive all the benefits and privileges accorded to its members upon 32 payment of the required fees and dues. Membership to the foregoing shall not be a bar 33 to membership in any other association of pharmacists. 34

35 Sec. 44. – *Membership to the Accredited Integrated National Professional* 36 *Organization.* – All registered pharmacists (and pharmacy assistants) must be members 37 of the AINO and must maintain membership throughout the duration of the practice of 38 the profession. Professional identification card shall not be renewed if the requirements 39 for membership with AINO are not met including credit units for attendance to duly 40 accredited continuing professional development (CPD) education activities.

41 Sec. 45. – Specialty Boards in Various Areas of Pharmacy Practice. – Specialty Boards 42 created within the affiliate organizations and societies for recognition of the AINO (1) 43 for the Board, subject to the approval of the Commissioner shall accredit specialties in 44 various areas of practice, (2) setting standards of practice within different specialties, 45 and (3) establishing qualifications and requirements for certification of practitioners 46 under each specialty.

ARTICLE VI

VIOLATIONS, ADMINISTRATIVE SANCTIONS, AND PROCEDURES

1 2

Sec. 46. – 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:

- 8 (a) Violation of this Act on unauthorized practice of pharmacy, violation of any 9 provision of this Act, the Rules and Regulations (RR) thereof, the Code of 10 Ethics for Pharmacists, Code of Good Governance, Code of Technical 11 Standards for the practice of pharmacy, policy, and measure of the Board 12 and/or the Commission;
- 13 (b) Malpractice or gross incompetence; negligence, or imprudence resulting to 14 death or injury of the patient;
- 15 (c) Dishonorable conduct and/or conviction by a competent court of any
 16 criminal offense involving moral turpitude;
- 17 (d) Fraud or deceit in the acquisition of the certificate of registration, professional
 18 identification card or temporary/special permit or renewal of license;
- 19 (e) Display of certificate of registration of a pharmacist who is not actually 20 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;
- 26 (h) Acting as a dummy of an alien or a person who is not qualified to establish
 27 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;
- 33 (k) Manufacture, sale, offering for sale of counterfeit drugs and committing other
 34 acts in violation of Sec. 4 of the Special Law on Counterfeit Drugs, R.A. No.
 35 8203;
- 36 (l) Illegal manufacturing, sale, possession, dispensing of dangerous drugs and
 37 other pertinent acts in violation of Dangerous Drugs Act, R.A. No. 9165;
- 38 (m) Committing acts in violation of Sec. 6 of P.D. No. 881 on Hazardous
 39 Substances; and

- 1 (n) Practicing pharmacy while under suspension.
- 2 (o) Practicing with an expired professional identification card.

Section 47. - Non-renewal of license. - The following are the grounds for the non renewal of professional identification card:

- 5 (a) Refusal to join or to remain a member of good standing of the AINO;
- 6 (b) Non-payment of annual registration fees for three (3) continuous years;

9 The Board shall periodically evaluate the aforementioned grounds and revise as the 10 need arises subject to the approval of the Commission.

Any person, entity or organization may file charges according to the provision of this 11 section against any registrant, or the Board may investigate violation of any of the 12 13 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 14 Legal and Investigation Office. The move to conduct an investigation shall be embodied 15 16 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 17 hearing or investigation subject to applicable provisions of this Act, R.A. No. 8981 and 18 its rules and regulations thereof, and Rules of Court. 19

- Sec. 48. Administrative Investigation/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.
- 24 If the Board, by a majority vote of the members, shall find that the charges are sustained 25 by evidence adduced, it may, at its discretion reprimand the respondent or revoke or
- 26 suspend his certificate of registration.

Sec. 49. - Procedure and Rules. - 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

31 is a valid ground to the charge, it shall conduct a formal investigation and set the dates 32 of the hearing thereof. For this purpose, a subpoena and/or subpoena *duces tecum* may 33 be issued by the chairman of the Board or by the Chief, Legal and Investigation 34 Division. The investigation proceedings shall at all times be recorded. The investigation 35 shall have been terminated and resolved within ninety (90) days from the time the first 36 date of hearing shall be set and heard.

Sec. 50. - *Rights of Respondent*. - The respondent pharmacist is entitled to be heard or
be represented by counsel; to have speedy public hearing, to confront, and to crossexamine the witness or witnesses against him; to summon and present witness or
witnesses in his behalf; or to avail himself/herself of any other process for the
protection of his/her constitutional rights

 ^{7 (}c) Non-compliance with the continuing professional development requirement,
 8 for the renewal of his/her professional identification card; and

Sec. 51. - Motion for Reconsideration. - A motion for reconsideration within the
 prescribed period may be made based on any of the following grounds:

3 (a) Grave abuse of discretion by the Board,

4 (b) Findings not supported by substantial evidence, and Irregularity in the conduct 5 of investigation.

6 Sec. 52. – Appeal/Finality of Decision. - The decision of the Board shall automatically 7 become final and executory fifteen (15) days from the appropriate service of the 8 decision to the respondent, unless the latter within the same period, has appealed the 9 decision to the Commission; provided that said decision of the Board and/or the 10 Commission may be appealed to the Court of Appeals.

11 12

ARTICLE VII PENAL PROVISIONS

Sec. 53. - *Penal Provisions.* - Any person who shall violate any of the provisions of the
 practice of pharmacy as defined in the following provisions of Article IV:

- 15 Registration certificate (Section 32)
- 16 (a) Allowing the display of his/her registration certificate in an outlet or 17 establishment by a pharmacist where he/she is not employed
- (b) Display of a pharmacist's registration certificate by an outlet or establishment
 when the pharmacist is not employed
- 20 Dispensing and compounding (Sections 27, 33, 38, 42)
- (c) Dispensing done in, or offering for sale of prescription drugs in a place not
 licensed by FDA as drug outlet
- (d) Dispensing of prescription of and pharmacist-only over-the-counter drugs by a
 person other than a registered pharmacist
- 25 (e) Dispensing of prescription drugs without presentation of a valid prescription
- (f) Compounding of prescription drugs and pharmacist-only over-the-counter
 drugs done by a person other than a pharmacist
- (g) Selling of prescription and pharmacist-only over-the-counter drugs by
 manufacturers, importers, and wholesalers to unlicensed drug outlets and other
 drug establishments
- (h) Substitution of prescription drugs which are not generically equivalent to what
 was on the prescription without the consent of the prescriber
- (i) Compounding not in accordance with the current Good Manufacturing Practices
 and Good Pharmacy Practice
- (j) Forcing, coercing or intimidating a registered pharmacist to compound or
 dispense drugs not in accordance with this Act

- (k) Preparation and compounding of pharmaceutical products in quantities greatly in excess of single therapeutic doses without a registered pharmacist
- (l) Non-compliance with the labeling requirement for dispensed medicines by a drug outlet
- (m) Allowing pharmacy assistants to dispense without the supervision of a pharmacist
- 7 Requirement of Pharmacist (Sections 33,34, 36)

1

2

3

4

5

- 8 (n) Establishment/outlet selling prescription and pharmacist-only over-the-counter 9 drugs which opens for business without a licensed pharmacist
- 10 (o) Compounding by a non-registered pharmacist or pharmacist with 11 expired/revoked/suspended license
- (p) Filling of prescription by a non-pharmacist or by a non-registered pharmacist or
 pharmacist with expired/revoked/suspended license
- 14 (q) Wholesale of pharmaceutical products without the direct and immediate 15 supervision of a registered pharmacist
- (r) Rural Health Units dispensing prescription drugs and pharmacist-only over-the-16 counter drugs without the supervision of a registered pharmacist Manufacturing 17 and selling of pharmaceutical products under fraudulent name and address (Section 35) 18 Adulteration and misbranding of drugs (Section 35) Manufacturing and selling of 19 unsafe and substandard drugs (Section 35) shall upon conviction thereof, be 20 sentenced to a fine of not less than Two Hundred Fifty Thousand 21 (Php250,000.00) Pesos but not exceeding Five Hundred 22 Thousand (Php500,000.00) Pesos and/or to an imprisonment of not less than one year and 23 one day but not more than six years, or both fine and penalty, at the discretion of 24 the court. 25
- 26 **Sec. 54.** *Other Penalties.* Any person who shall violate any of the following 27 provisions of this Act:
- (a) 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)
- 30 (b) Practice of pharmacy in the Philippines by a foreigner without special permit31 (Section 28)
- (c) Non-indication by a pharmacist of his/her registration number and Professional
 Tax Receipt number in official documents requiring such information (Section
 30)
- 35 (d) Non-display of certificate of registration of a pharmacist in drug establishment
 36 requiring such (Section 32)
- 37 (e) Non-display of certificate of registration of a pharmacist by an
 38 establishment/outlet (Section 32)

- 1 (f) Non-compliance with this Act's provision on the required salary for a registered 2 pharmacist (Section 34)
- 3 (g) Non-compliance by a pharmacist with the requirement on the filling of
 4 prescription (Section 36)
- (h) Non-compliance by a registered pharmacist on the requirement for partially
 filled prescription (Section 36)
- 7 (i) Selling of physician's samples (Section 37)

30

31

- 8 (j) The removal, erasure and alteration of mark or label of physician's sample 9 (Section 37)
- 10 (k) Non-compliance with the filling up of Record Books by a drug outlet (Section 40)
- 11 (1) Employment of persons in a pharmacy without the provision of the required 12 training (Section 42)
- 13 (m) Rendering dispensing-related services by non-pharmacists in a drug outlet 14 without undergoing the required training (Section 42) shall upon conviction 15 thereof, be sentenced to a fine of not less than One Hundred Thousand 16 (Php100,000.00) Pesos but not exceeding Two Hundred Thousand 17 (Php200,000.00) Pesos or to an imprisonment of not less than Thirty (30) days 18 but not more than One (1) year, or both fine and penalty at the discretion of the 19 court.
- 20 Any person other than the citizens of the Philippines having been found 21 guilty of any violation as provided for in this and the preceding section shall, 22 after having paid the fine or having served his sentence or both when so 23 adjudged, be also subject to immediate deportation.
- For any violation of the provisions of this Act penalized under this and the preceding section, which also constitutes or considered as punishable offense or described as a violation of other laws, the applicable penalty shall be that of the law providing for a higher fine and/or imprisonment.
- For any violation of the rules and regulations implementing the provisions of this Act, appropriate penalty shall be imposed.

ARTICLE VIII

FINAL PROVISIONS

- 32 Sec. 55. Enforcement. The Commission shall be the enforcement agency of this Act. 33 As such, the Commission shall implement the appropriate provisions of this Act, 34 enforce its implementing rules and regulations as adopted by the Board, assist the 35 Board in the investigation of complaints against violators of this Act, its rules and 36 regulations, Code of Ethics for pharmacists, professional standards, and other policies 37 of the Board and the Commission.
- The Commission and/or the Board shall call upon or request any department, instrumentality, office, bureau, institution or agency of the government, including local government units to render such assistance as it may require, or to coordinate or cooperate in order to carry out, enforce or implement the provisions of this Act.

Sec. 56. - Appropriations. - The Chairperson of the PRC 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.

5 Sec. 57. - Implementing Rules and Regulations. - Within one hundred and twenty (120) 6 days after the approval of this Act, the Board subject to the approval by the 7 Commission, in consultation with the AINO, shall issue and formulate the rules and 8 regulations, the Code of Ethics and professional standards for pharmacists, to 9 effectively implement this Act.

10 Sec. 58. - Separability Clause. - If any clause, provisions, paragraph or part

11 hereof shall be declared unconstitutional or invalid, such judgment shall not affect,

invalidate, impair any other part thereof, but such judgment shall be merely confined to
 the clause, provision, paragraph or part directly involved in the controversy in which
 such judgment has been rendered.

Sec. 59. - Repealing clause. - R.A. No. 5921, known as the Pharmacy Law, as amended by E.O. No. 174, and PD No. 1363, and all other laws are hereby repealed, Presidential decrees, executive orders, and other administrative issuances and parts thereof which are inconsistent with the provisions of this Act are hereby modified, amended, superseded or repealed accordingly.

Sec. 60. - *Effectivity*. - This Act shall take effect after fifteen (15) days following the full
 and complete publication thereof in the Official Gazette or in any major daily
 newspaper of general circulation in the Philippines.

23 Approved,