

Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

3rd Floor, PDEA Building
National Government Center, NIA Northside Road, Pinyahan
Quezon City

BOARD REGULATION No. ___

Series of 2013

SUBJECT: Comprehensive Amendments to Board Regulation No. 3 Series 2003, "Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other Lawful Acts in Connection with Any Dangerous Drugs, Controlled Precursors and Essential Chemicals and Other Similar or Analogous Substances", as Amended, and Other Related Board Issuances

Pursuant to Section 2, Sections 12, 16, and 32, of Article II, Section 40 of Article III, Section 81(b) and (r) of Article IX and Section 93 of Article XI of RA 9165, the following guidelines are hereby promulgated:

ARTICLE I
Definition of Terms

Section 1. Definitions.

In this Guidelines, unless the context indicates otherwise.

(a) "Act" refers to Republic Act No. 9165, otherwise known as the "Comprehensive Dangerous Drugs Act of 2002".

(b) "Administer" means any act of introducing any dangerous drug into the body of any person or animal, with or without his/her knowledge by injection, inhalation, ingestion or other means, or of committing any act of indispensable assistance to a person in administering a dangerous drug to himself/herself unless administered by a duly licensed practitioner for purposes of medication.

(c) "Analogue" means any substance whose chemical structure is substantially similar to any dangerous drug whose psychoactive effects it simulates.

(d) "Article" means a manufactured item other than a fluid or particle; (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and does not pose a physical hazard or health risk to employees.

(e) "Board" or "DDB" refers to the Dangerous Drugs Board under Section 77, Article IX of RA 9165.

(f) "Bulk quantity delivery" means quantities:

(i) equal to or more than 500 kilograms or liters of controlled chemical.

(ii) equal to or more than one kilogram of dangerous drug or its preparation.

(g) "Chemical mixture" means a combination of two or more chemical substances, at least one of which is not a controlled chemical, and except that such term does not include any combination of controlled chemical with another chemical that is present solely as an impurity.

(h) "Commercial Broker" or "Indentor" means one who, for compensation, acts as a middleman in bringing about a purchase and sale of goods between a foreign supplier and a local purchaser; a person

who merely act as intermediary or middle-man in effecting a sale, and act in a certain sense as the agent of both parties to the transaction.

(i) "Completely formulated paint or coating" is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application;

(j) "Controlled chemical" means a substance listed as controlled precursor and essential chemical as defined pursuant to Section 3(h), Article I, RA 9165 and include those classified as such by the Dangerous Drugs Board pursuant to Section 93 Article XI of RA 9165 for domestic control.

(k) "Controlled Laboratory equipment" means the paraphernalia, apparatus, materials or appliances when used, intended for use or designed for use in the manufacture of any dangerous drug and/or controlled precursor and essential chemical, such as reaction vessel, preparative/purifying equipment, fermentors, separatory funnel flask, heating mantle, gas generator, condenser, or their substitute;

(l) "Controlled substance" means either a dangerous drugs or a controlled precursors and essential chemicals.

(m) "Controlled substance trader" means any establishment which is a registered owner of a health product and procures the raw materials and packing components and provides the production monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products. A controlled substance trader shall be categorized as a manufacturer under this Regulation.

(n) "Customs broker," means any person who is bona fide holder of a valid Certificate of Registration/Professional Identification Card issued by the Professional Regulatory Board and Professional Regulation Commission; a licensed agent or broker whose function is to handle the process of clearing goods through customs.

(o) "Dangerous drugs" include those listed in the Schedules annexed to the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and in the Schedules annexed to the 1971 Single Convention on Psychotropic Substances as enumerated in the attached annex which is an integral part of RA 9165 and include those classified as such by the Dangerous Drugs Board pursuant to Section 93 Article XI of RA 9165 for domestic control.

(p) "Dispense" means any act of giving away, selling or distributing medicine or any dangerous drug or with the use of prescription by a PDEA - licensed practitioner.

(q) "Diversion of dangerous drugs" means the unlawful obtaining and channeling of pharmaceutical dangerous drugs for illegal purposes among others e.g. in drug dens, dives or resorts and any other places by methods such as forged or altered prescription, feigning sickness and obtaining prescription from many medical practitioners, theft and robbery, fraudulent import permit, over prescription by medical practitioners, doctors shopping, collection of drug leftovers and unused prepared parenteral dose in hospitals, obtaining drugs via e-mail and post, use of invalidated local order form instead of prescription form.

(r) "DOH" means Department of Health.

(s) "Drug" means: (1) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (4) articles intended for use as a component of any articles specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories.

(t) "Drug product" means finished dosage form that contains a drug substance that may or may not be in association with other active or inactive ingredients.

(u) “End-user declaration” refers to a signed declaration, by both the purchaser and end-user in a transaction stating the intended use of the chemical product/apparatus and that it will not be used for the manufacture of illicit drugs. End-user declaration is provided together with an order, bearing official company stationery.

(v) “End-user license” authorizes the holder to acquire controlled chemicals from a licensed importer or manufacturer or wholesaler or through import for legitimate use in the course of commercial or industrial operation such as but not exclusive to manufacture or production processes. The certificate holder is NOT authorized to resell such chemical in original form to others. He may dispose the chemical waste resulting from the commercial or industrial operation to a PDEA licensed recycler.

(w) “Entity” means any person, natural or juridical, including among others, a corporation, partnership, trust or estate, joint stock company, association, joint venture or other unincorporated organization or group capable of acquiring rights or entering into obligations.

(x) “Export,” means any physical departure of dangerous drugs or controlled chemicals or other goods from the customs territory of the country, which requires customs declaration.

(y) “FDA” means Food and Drug Administration of the Philippines

(z) “Foreign State” means:

(i) Any country other than the Philippines; and

(ii) Every constituent part of such country, including a territory, dependency or protectorate, which administers its own laws relating to dangerous drugs, analogues, and controlled equipment and chemicals.

(aa) “Generic Drug” means a drug which is the same as a brand named drug or innovator product, having the same active ingredient, dosage form, safety, strength, how it is taken, quality, performance, and intended use and which is approved by the Food and Drug Administration.

(bb) “GHS” is an acronym for Globally Harmonized System of Classification and Labeling of Chemicals. The GHS is a system for standardizing and harmonizing the classification and labeling of chemicals. It is a logical and comprehensive approach to:

(i) Defining health, physical and environmental hazards of chemicals;

(ii) Creating classification processes that use available data on chemicals for comparison with the defined hazard criteria; and

(iii) Communicating hazard information, as well as protective measures, on labels and Safety Data Sheets (SDS).

(cc) “Hazards” refer to the inherent characteristics of chemical substances and mixtures that exist in the workplace and in the environment regardless of quantity that are potentially dangerous or which have the capacity to harm, i.e., its capacity to interfere with normal biological processes, and its capacity to burn, explode, corrode, etc.

(dd) “Hazardous or toxic substances” refer to the chemical substances or mixtures that may be harmful to the environment and/or to human health in a short-term and long-term basis if it is inhaled, swallowed, or absorbed through the skin.

(ee) “Hospital” means a facility

(i) that is licensed, approved or designated by the DOH or Bureau of Animal Industry to provide care or treatment to persons or animals suffering from any form of disease or illness, or

(ii) that is owned or operated by the Government of the Philippines or the government of a province or city/municipality and that provides health services.

(ff) “**Illegal Trading**” means transactions involving illegal trafficking of dangerous drugs and/or controlled precursors and essential chemicals using electronic devices such as, but not limited to,

text messages, e-mail, mobile or landlines, two-way radios, internet, instant messengers and chat rooms or acting as a broker in any such transactions whether for money or any other consideration in violation of this Act.

(gg) "Import" means any physical introduction of dangerous drugs or controlled chemicals or other goods into the customs territory of the country, which requires declaration.

(hh) "Institution" means a licensed hospital, nursing home or other institution used for the accommodation, treatment and care of persons or animals suffering from physical or mental conditions.

(ii) "International Drug Control Conventions" means the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol amending the Single Convention; the 1971 Convention on Psychotropic Substances; the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances; and any other international convention to which the Philippines is a Party or may become a Party after the commencement of Republic Act 9165, relating in whole or in part to the control of dangerous drugs and controlled chemicals.

(jj) "Intractable pain" means a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the practitioner's medical records.

(kk) 'In-vitro diagnostic reagents' are reagents and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae.

(ll) "Label" refers to an appropriate group of written, printed or graphic information elements that are affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product.

(mm) "License" means a written permission or authorization.

(i) S-License refers to dangerous drug and their preparations and authorized activities for holders;

(ii) P-License refers to controlled precursors and essential chemicals and mixtures and authorized activities for holders.

(nn) "Licensing" refers to the process involving the grant, registration, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification or conditioning of a license.

(oo) "Mail or postal matters" shall refer to all matters authorized by the Government to be delivered through the postal service and shall include letters, parcels, printed materials, and money orders.

(pp) "Manufacture" means the production, preparation, compounding or processing of any dangerous drug and/or controlled precursor and essential chemical, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, and shall include any packaging or repackaging of such substances, design or configuration of its form, or labeling or relabeling of its container; except that such terms do not include the preparation, compounding, packaging or labeling of a drug or other substances by a duly authorized practitioner as an incident to his/her administration or dispensation of such drug or substance in the course of his/her professional practice including research, teaching and chemical analysis of dangerous drugs of such substances that are not intended for sale or for any other purpose.

(qq) "Medical practitioner" means any person who is registered and entitled under the laws of the Philippines to practice the profession of medicine, to include dentistry and veterinary medicine.

(rr) "Material Safety Data Sheet or MSDS" or "Safety Data Sheet or SDS" is (i) widely used system for cataloguing information on chemicals, chemical compounds and/or mixtures which contains information on the proper procedure for the handling of a particular substance, safe use, first aid, potential hazards, physical data, proper storage requirement, disposal, protective equipment, spill/leak procedures among others; (ii) a document that provides important physical characteristics, ecological,

health, safety and toxicological information on chemical substances or mixtures of ingredients used at the workplace, transported and may be utilized by the consumer.

(ss) "Operator" means any person who carries on a business of the importation, exportation, manufacture, dispensation, end-use, research, acquisition or sale/supply of:

(i) A dangerous drug for medical, scientific use or other lawful use; or

(ii) A controlled chemical, intended for lawful use, or a related business, such as import, export, transit, processing or acting as a commercial broker or indentor, but excludes person carrying on a business of customs brokerage agent, warehouse depositor or carrier when acting solely in that capacity.

(tt) "Opioid" means any morphine-like synthetic narcotic that produces the same effects as drugs derived from the opium poppy (opiates), such as pain relief, sedation, constipation and respiratory depression.

(uu) "Parcel" means an object article container or quantity of something wrapped or packed up small package bundle e.g. a box, the dimension and weight of which is as specified by the Corporation or the Government containing goods or some form of transportable property intended for delivery to an addressee prominently displayed on at least one (1) of its sides.

(vv) "Patient" means any human or animal recipient of health care services. The patient is most often ill or injured and in need of treatment by a physician, or a dentist, or a veterinarian, or other health care provider.

(ww) "Permit" means an authorization granted in writing by the Director General PDEA or his authorized representative to a license holder for the importation, exportation and other activities requiring such a permit, of a controlled substance.

(xx) "Person" means any entity, natural or juridical, including among others, a corporation, partnership, trust or estate, joint stock company, association, joint venture or other unincorporated organization or group capable of acquiring rights or entering into obligations.

(yy) "Pharmacist" means any person who is registered and entitled under the laws of Philippines to practice the profession of pharmacy.

(zz) "PDEA" refers to the Philippine Drug Enforcement Agency as provided for in Section 83 Article IX of RA 9165.

(aaa) "PDEA-CS" refers to PDEA Compliance Service as provided for in Paragraph III, Section 83, Article IX of RA 9165.

(bbb) "Place" includes any land (whether vacant enclosed or built upon, or not), and any premises.

(ccc) "Prescription" means a written direction by a medical practitioner that a stated quantity of a dangerous drug in any form or drug in parenteral form containing controlled chemical, be dispensed for the patient named therein.

(ddd) "Preparation" means a solution or mixture, in whatever physical state, containing:

(i) A dangerous drug; or

(ii) A controlled chemical.

(eee) "Proceedings" means any administrative or quasi-judicial procedure conducted by a government agency, the Board and PDEA and includes an inquiry, investigation, or preliminary or final determination of facts.

(fff) "Recycler" means a commercial enterprise that acquires waste containing controlled chemicals, removes unwanted chemicals entirely or partially and then resells the processed controlled chemicals;

(ggg) "Regulatory Compliance Officer" means any person appointed and/or designated as such by the PDEA pursuant to Article IV of this Regulation.

(hhh) "Retail distributing," means the selling is limited almost exclusively for personal use, both in number of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. The person buying from the retailer is the ultimate user or consumer of the article or commodity or does not sell it again.

(iii) "Sell," means any act of giving away any dangerous drug and/or controlled precursor and essential chemical whether for money or any other consideration.

(jjj) "Special Prescription Form for dangerous drugs" means the prescription form for dangerous drugs that is made of a special kind of paper exclusively issued by and obtainable from DOH.

(kkk) "Supply" includes sale, shipment, dispatch, transport, delivery, distribution, dispensing, as well as offer to supply.

(III) "Table I Controlled Chemical" means chemicals enumerated in the list of substances in Table I of the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which is an integral part of the Act. Table I Precursor chemical means a chemical or a raw material that is specific and critical in the manufacture of a narcotic and/or psychotropic drug and becomes incorporated into the drug molecule of the finished product.

(mmm) "Table II Controlled Chemical" means chemicals enumerated in the list of substances in Table II of the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which is an integral part of the Act.

(nnn) "Table III Controlled Chemical" means chemicals classified as controlled chemical in accordance with Section 93 Article XI of the Act for domestic control.

(ooo) "Test Kit" means a substance

(i) that contains reagent systems or buffering agents or both to show the presence of a substance,

(ii) that is used in the course of a chemical or analytical procedure for medical, laboratory, industrial, educational or research purposes, and

(iii) the contents of which are not intended for administration to humans.

(ppp) "The 1961 UN Convention" means the Single Convention on Narcotic Drugs, 1961-United Nations as amended by the 1972 Protocol.

(qqq) "The 1971 UN Convention" means the Convention on Psychotropic Substances, 1971-United Nations.

(rrr) "The 1988 UN Convention" means the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

(sss) "Transit" means any transport of dangerous drugs or controlled chemicals between third countries through the customs territory of the Philippines and any transshipment in the Philippines;

(ttt) "Therapeutic dose" means that quantity which is required to elicit the desired therapeutic response in the individual in the treatment of disease or ailment.

(uuu) "Transcribing" means the act of transferring a medication order from the original prescription to the current administration record/prescription sheet.

(vvv) "Ultimate user" means a person who has lawfully obtained, and possesses either;

(a) a dangerous drug preparation for his own use or for an animal owned by him; or

(b) a controlled chemical preparation or product for his own household consumption use

(www) "Uniformed Service" means Armed Forces, National Police and Coast Guard of the Philippines and foreign countries.

(xxx) "UN Number" means the identification serial number assigned to any chemical or hazardous material by the United Nations (UN) Committee of Experts on the transportation of these materials and as published in the UN recommendations on the transport of dangerous goods.

(yyy) "Use" means any act of injecting, intravenously or intramuscularly, of consuming, either by chewing, smoking, sniffing, eating, swallowing, drinking or otherwise introducing into the physiological system of the body, any of the dangerous drugs and/or drug preparations containing controlled chemical.

(zzz) "Veterinarian" means any person who is registered and entitled under the laws of the Philippine to practice the profession of veterinary medicine.

(aaaa) "Volatile substances" means and include any liquid, solid or mixed substance having the property of releasing toxic vapors or fumes containing one or more of the following chemical compounds: methanol, ethanol, isopropanol, ethyl acetate, n-propyl acetate, n-butyl acetate, acetone, methyl ethyl ketone, methyl butyl ketone, benzene, toluene, xylene, styrene, naphthalene, n-pentane, n-hexane, n-heptane, methylene chloride, trichloroethylene, tetrachloroethylene, nitrous oxide, dichlorodifluoromethane, chlorodifluoromethane, isoamyl nitrate, ether or chloroform or any other chemical substance, which when sniffed, smelled, inhaled, or introduced into the physiological system of the body produces or induces a condition of intoxication, inebriation, excitement, stupefaction, dulling of the brain or nervous system, depression, giddiness, paralysis, or irrational behaviour or in any manner changing, distorting or disturbing the auditory, visual or mental processes, as provided for in Presidential Decree No 1619.

(bbbb) "Wasting" means an occurrence when a controlled substance removed from the original container that has become contaminated or have otherwise become unusable.

(cccc) "Wholesale distributing," means activities by any person, which stands between the manufacturer and the retail seller in purchases, shipments, or contracts for sale of a controlled substance.

ARTICLE II CLASSIFICATION

Section 2. Classification of Dangerous Drugs and Controlled Precursors and Essential Chemicals

(1) Each of the drugs classified as scheduled dangerous drugs appears under its international non-proprietary name or, lacking such a name, under its scientific name. Dangerous drugs and their preparations may also appear under their generic and common trade names. Dangerous drugs and their preparations introduced in the Philippines for medical, dental, veterinary practice use and research purposes shall be registered with the Food and Drugs Administration. Refer to Annex A for the Philippine Schedules.

(2) All substances classified by the Board as a dangerous drug pursuant to Section 93 of the Act, for domestic control, shall likewise be categorized under the Philippine Schedule 5

(3) Each of the chemicals classified as Table I, Table II and Table III controlled precursor and essential chemical appears under its chemical name and its Chemical Abstract Service Number, other names or synonyms of the chemical or commercial name or common trade names. Drugs containing controlled chemical introduced in the Philippines for medical, dental, veterinary, and research purposes shall be registered with the Food and Drugs Administration. (Refer to Annex B)

Section 3. Reclassification, Addition or Delisting/Removal of Any Drug from the List of Dangerous Drugs

(1) Pursuant to Section 93 of Article XI of the Act:

(a) The Board shall have the power to reclassify, add to or remove from the list of controlled substance.

(i). “ Notifications, communicated by the Secretary General of the United Nations to the Board, through the Department of Foreign Affairs, of decisions to include a substance in the Schedule or Table of international controlled substances under the international drug control conventions shall obligate DDB under the 1961 UN Convention, to automatically issue an Implementing Board Regulation to declare such substance as included in the lists of dangerous drugs or controlled precursors and essential chemical provided that no objections or reservations is received within 180 days by the DDB. Likewise, the DDB shall automatically issue an implementing Board Regulation when the United Nations declares a controlled substance excluded from international control.”

(ii) Proceedings to reclassify, add, or remove a drug or other substance may be initiated by the PDEA, the DOH, or by petition from any interested party, including manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a national or local government agency, or an individual citizen. When the Board receives a petition, it shall immediately begin its own investigation of the drug. The PDEA also may begin an investigation of a drug at any time based upon the information received from law enforcement laboratories, national and local law enforcement and regulatory agencies, or other sources of information.

For the recommended public hearing proceedings, refer to Annex C

(b) The Board after notice and hearing shall consider at its public hearing the following factors in determining whether a substance should be reclassified, added or removed from regulatory control:

- (i) its actual or relative or degree of potential for abuse;
- (ii) scientific evidence of its pharmacological effect if known;
- (iii) the state of current scientific knowledge regarding the drug or other substance;
- (iv) its history and current pattern of abuse;
- (v) the scope, duration, and significance of abuse;
- (vi) risk and benefit to public health;
- (vii) whether the substance is an immediate precursor of a substance already controlled under the Act;

(c) The Board shall also take into account the obligations and commitments to international treaties, conventions and agreements to which the Philippines is a signatory.

(d) The Board shall give notice to the general public of the public hearing of the reclassification, addition to or removal from the list of any drug by publishing such notice in any newspaper of general circulation once a week for two (2) consecutive weeks.

(e) The effect of such reclassification, addition or removal shall be as follows:

- (i) in case a dangerous drug is reclassified as precursors and essential chemicals, the penalties for the violations of the Act, involving the two latter categories of drugs shall, in case of conviction, be imposed in all pending criminal prosecutions;
- (ii) in case a precursor and essential chemicals is reclassified as dangerous drug, the penalties for violations of the Act, involving precursors and essentials shall, in case of conviction, be imposed in all pending criminal prosecutions;
- (iii) in case of addition of a new drug to the list of dangerous drugs and precursors and essential chemicals, no criminal liability involving the same under The Act shall arise until the lapse of fifteen (15) days from the last publication of such notice;
- (iv) in case of removal of a drug from the list of dangerous drugs and precursors and essential chemicals, all persons convicted and/or detained for the use and/or possession of such drug

shall be automatically released and all pending criminal prosecution involving such a drug under The Act shall forthwith be dismissed;

(v) the Board shall, within five (5) days from the date of its promulgation submit to Congress a detailed reclassification, addition, or removal of any drug from the list of dangerous drugs. The Executive Director shall provide such list to the Director General, PDEA.

(2) For the purpose of public hearing, the Board may convene a Technical Working Group, which shall consist of a representative each from the Board Secretariat, PDEA, Food and Drug Administration, National Center for Pharmaceutical Access and Management of the Department of Health, NBI, PNP Crime Laboratory, UP-PGH National Poison Management and Control Center and Department of Justice, as permanent regular members. The Board may invite resource persons from the field of drugs and chemical control for consultation meeting. A representative from the Board Secretariat, designated by the Board, shall preside over the meetings. The Technical Working Group shall gather and collate all data relative to the drug and chemical under consideration and submit a report of its findings and recommendations to the Board.

(3) Any person may petition the DDB through the Executive Director, for adoption, amendment or repeal of a Regulation reclassifying a substance. DDB shall respond to a petition within fifteen (15) working days, giving reasons for its response.

Section 4. Preparations

(1) Unless exempted from certain measures of regulatory control, preparations/mixtures/ products shall be subject to the same measures of control under this Regulation as the controlled substance it contains.

(2) The Board may exempt from specific measures of regulatory control requirements any preparation containing:

(a) a dangerous drugs in Philippine Schedules 4 and 5, when the Board is satisfied that:

(i) the preparation is not in parenteral form and is compounded in such a way as to present no or negligible risk of abuse;

(ii) the preparation does not contain more than one dangerous drug;

(iii) the dangerous drugs cannot be readily recovered from it in a quantity liable to present such a risk;

(iv) the exemption is necessary for a medical or scientific purpose and is otherwise in the public interest;

(b) a drug preparation containing a controlled chemical unless:

(i) the drug preparation is in parenteral form; or,

(ii) if it has been determined that the drug or group of drugs is being diverted to obtain the controlled chemical for use in the illicit manufacture of a dangerous drug;

(c) solid, semisolid and highly viscous chemical mixture containing Table II controlled chemical;

(d) when the Board is satisfied that the mixture is formulated in such a way that the controlled chemical cannot easily be used for the illicit manufacture of a dangerous drug and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered.

(3.) Mixtures containing a controlled chemical in concentrations equal to or less than those specified in the "Table of Concentration Limits" are automatically exempt from specified control measures as provided in the succeeding Sections of this Regulation. The concentration is determined for liquid-liquid mixtures by using the volume or weight and for mixtures containing solids or gases by using the unit of weight. (Refer to the Table of Concentration Limits in Annex D)

(4). In application of Section 4(2)(a)

(a) All oral forms of FDA-registered drug preparations in Philippine Schedule 4 and 5 are exempted from the Special Prescription Form for dangerous drugs but must be prescribed in an ordinary prescription in triplicate copies. The same drugs are also exempted from the local order permit requirement for transactions between a wholesale distributor and retail drugstore, and hospital pharmacy.

(b) in vitro diagnostic reagents, buffers and analytical standards and test kits containing dangerous drug for diagnostic test to determine drugs in body fluids or nature of disease are exempted from all regulatory requirements, except registration and license of importer. Importation made shall be reported to PDEA within five (5) working days upon arrival of the shipment.

(5). In application of Section 4(2)(b), FDA-registered pharmaceutical oral drug preparations containing ergometrine/ergonovine, ergotamine, norephedrine and their salts, and compounded galenical preparations (solutions) containing potassium permanganate intended as disinfectant, antibacterial and antifungal agents are exempted from all regulatory requirements except registration and license of importer, exporter and manufacturer. Where importation of finished product exceeds the following equivalent quantities of 0.010 grams for ergometrine/ergonovine, 0.020 grams ergotamine, 2.5 kilograms for norephedrine and 1 kilogram for potassium permanganate per importation, an import permit shall be required. Each import or export transaction shall be reported to PDEA not later than five (5) working days before date of importation or exportation of the shipment. Prescription, dispensing and reporting requirements for the drug preparations shall be subject to FDA Rules and Regulations.

(6) In application of Sections 4(2)(c) and 4(2)(d) the following categories of chemical mixtures in concentration equal to or less than those specified in the "Table of Concentration Limits" or unless otherwise specified, that is contained in articles or finished products intended for sale to the general public, except as otherwise banned by the Food and Drug Administration in case of food and cosmetics or the Department of Health in case of household hazardous substance or by the Department of Environment and Natural Resources and the Department of Trade and Industry are exempted from all regulatory requirements under this Regulation, excluding registration of license of manufacturer, and recording and reporting of acquisition and usage of raw material by manufacturer.

(a) completely formulated paints, that contain all of the components of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. Included but not exclusive to, in this category are clear coats, top-coats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film-forming agents, epoxies, vinyl, lacquer, contact cements, waxes, cleaning agents. Toluene is banned in spray paints and glue at concentrations equal to or higher than 0.1 per cent by weight, that is intended for sale to the general public;

(b) products containing Acetic Anhydride such as silicone product that is a sealant, adhesive or coating;

(c) products containing Anthranilic Acid such as perfume and soya sauce;

(d) articles or products containing Acetone, such as beverages, baked foods, desserts, and preserves; various cosmetic products; food additives and food packaging; nail polish remover; superglue remover; skin adhesive remover; varnish removers and other paint related solutions; lacquers for automotive or furniture finishes; cellulose acetate films and fibers; photographic films and plates casting; coatings; inks; resin thinners; general purpose cements; degreasing and degumming agent; paint; varnish; lacquer strippers; cosmetic products; home products including nail polish, hair colors, hair tonics and conditioners, sun tan and other lotions applied on the skin, baby wipes, pre-moistened towels; art material including clay, finger paints, and tempera colors, paint thinners, leather shoes and dressings, shoe polishes and creamers, pet flea and tick products, pet collars, household surface cleaners, furniture polish and cleaners, particleboard furniture, cabinets or fixtures, wooden furniture, car polish and cleaners, insecticides and pesticides used at home and garden;

- (e) household products containing Hydrochloric Acid such as toilet bowl and drainage cleaner;
- (f) household products containing Methyl Ethyl Ketone such as lacquer, varnishes, paint remover, glues, polystyrene cement, cleaning agent, dry erase markers;
- (g) products containing Phenylacetic Acid such as perfume, bird and insect repellent;
- (h) products containing Piperidine such as rubber vulcanization accelerator;
- (i) products containing Piperonal such as synthetic vanilla flavour, candies, and perfume;
- (j) compounds containing Sulfuric such as drain and metal cleaners, anti-rust compounds and lead-acid (car) batteries containing less than 51 per cent sulfuric;
- (k) articles or products containing Toluene such as polystyrene kits; coatings for floors and furniture, artificial sports tracks, ski suits and waterproof leisure wear, nail cosmetics, adhesive remover intended for use on humans or animals, adhesive used on humans and animals, tape, contact paper, wallpaper, shelf liners, or any other product with an adhesive incorporated onto or in an inert substrate, spray paints and glue at concentrations less than 0.1 per cent by weight.
- (l) articles containing Thionyl Chloride such as lithium-thionyl chloride batteries.

(7). In application of Section 4(3) the chemical mixtures are exempted from all regulatory requirements under this Regulation, excluding registration of license of importer. Importation made shall be reported to PDEA within five (5) working days upon arrival of the shipment

- (a) Importation of chemical mixtures that contain acetone, ethyl ether, methyl ethyl ketone, toluene, hydrochloric acid, and sulfuric acid;
- (b) Chemical mixture that contain potassium permanganate;
- (c) Importations of preparations or mixtures of fragrances or flavorings containing anthranilic acid, phenylacetic acid, or piperidine intended to be used in a food, drug, cosmetic or household product.

(8). For the purpose of exempting controlled substances from specific regulatory requirements not covered under the Table of Concentration Limits in Annex D, the Board may convene a Technical Working Group- Exemption Committee, which shall consist of a representative each from the Board's Secretariat, PDEA, NBI and PNP Crime Laboratory. The Board may invite experts in the field of drugs and chemical control for consultation meeting. A representative from the Board's Secretariat, designated by the Board, shall preside over meetings of the Committee.

(9). The procedures for exempting dangerous drugs preparations, or controlled chemical or mixtures, or products containing Table I or Table II controlled chemicals from specific regulatory requirements are as follows:

- (a) Any manufacturer or importer seeking an exemption for a controlled substance or end-user of a controlled precursor and essential chemical from the application of all or any part of this Board Regulation, may apply to the Board through the Executive Director;
- (b) An application for exemption under this Section shall contain the following information;
 - (1) The name, address, and registration number, if any, of the applicant,
 - (2) The date of the application,
 - (3) The exact generic and/or brand/ trade name(s) of the applicant's dangerous drugs preparations, or controlled chemical or mixtures, or drug preparation (products) containing Table I or Table II controlled chemicals, and, if the applicant formulates or manufactures the dangerous drugs preparations, or controlled chemical or mixtures, or products containing Table I or Table II controlled chemicals for other entities, the exact generic and/or brand/ trade names of the dangerous drug preparation or chemical mixtures and the names of the

entities for which the dangerous drug preparation or chemical mixtures were manufactured for or prepared,

- (4) The complete qualitative and quantitative composition of the controlled substance issued by an accredited and independent laboratory institution.
- (5) The chemical and physical properties of the controlled substance and how they differ from the properties of the dangerous drugs or controlled chemicals, and
- (6) A statement that the applicant believes justifies an exemption for the controlled substance. The statement must explain how the following exemption criteria is met,
 - (i) The controlled substance is formulated in such a way that it cannot be easily used in the illicit production of a dangerous drug, and
 - (ii) The controlled substance cannot be readily recovered or extracted,
- (7) A statement that the applicant accepts the right of the Board to terminate exemption from regulation for the controlled substance granted exemption under this Section,
- (8) The full disclosure of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under Philippine laws restricting the public disclosure of such information. Members of the Technical Working Group of the Board shall strictly observe a “non-disclosure agreement”.

(c) All claims on the controlled substance will be validated with supporting documents which shall be certified to be true and correct by the submitting party.

(d) The Executive Director, DDB may require the applicant to submit such additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted;

(e) Within fifteen (15) working days after the receipt of an application for an exemption, Board through the Executive Director, will notify the applicant of acceptance or rejection of the application. If the application is not accepted, an explanation will be provided. The Executive Director, DDB is not required to accept an application if any information is lacking or not readily understood. The applicant may, however, correct the application to meet the prescribed requirements;

(f) Within ten (10) working days after receipt by DDB and acknowledged in writing by the applicant, the DDB shall convene the DDB Technical Working Group-Exemption Committee to evaluate the application for exemption. Said meeting shall be posted in its official website. The Board shall permit any interested party to file written comments on or objections to the proposed order within thirty (30) working days from the date of publication of the notification. Within twenty working (20) days thereafter, the TWG shall convene to consolidate comments or objections and re-evaluate the application. The DDB TWG shall be given ample time to submit its findings and recommendations to the Board.

(g) A manufacturer of an approved exempted controlled substance shall notify Executive Director, DDB and Director General, PDEA in writing, of any change in the quantitative or qualitative composition of the substance or product that has been granted an exemption by application. Changes include those greater than the range of concentration given in the application or that remove dangerous drugs or controlled chemical given in the application as part of the formulation. A new application will be required if reformulation results in a new product having a different commercial application or can no longer be defined as part of a group of an approved exempted dangerous drugs preparations, or controlled chemical or mixtures, or drug preparation containing Table I. DDB and PDEA must be notified in writing at least thirty (30) working days in advance of (i) reformulation of marketing the reformulated mixture, or (ii) effective date for the change in name or other designation, or any identifier.

(h) Certificate of exemption issued shall be valid until revoked.

(i) The Board may modify or recall exemptions granted on controlled substances, when it has established that the controlled substances is being diverted for the illicit manufacture of controlled substances and abuse.

(9) Exemption granted pursuant to this Section does not remove the criminal liability for illegal use or administration in drug dens, dives or resorts and illicit trafficking in controlled chemicals contained in the exempt chemical mixtures.

(10) The Board Secretariat shall maintain a register of the preparations it exempted under this Section, specifying in relation to each regulatory control measure from which it is exempted. The Executive Director, DDB shall provide the Director General, PDEA, a copy with every issuance of exemptions of preparations/mixtures/products from specified regulatory control for implementation.

ARTICLE III

REGISTRATION, LICENSING AND PERMIT SYSTEM

Section 5. Requirements for Registration/Licensing, Permit, /Authorization, etc, of Controlled Substance

(1) The applicable regulatory control measures or combination of such measures, which the PDEA shall impose, are the following:

- (a) registration and/or the grant of a license; or
- (b) in the case of import, transit, and export activities, registration and/or licensing, and;
 - (i) import, transit, and export permits issued to the operator by the PDEA for each of such activities;
 - (ii) a permit for each intended import or export transaction, or for each transit or redirection;
 - (iii) an export permit for each intended export transaction, conditional on the prior receipt of an import certificate issued by the competent authorities of the country of intended import;

(2) In application of this Section, the PDEA shall require all registered handlers the following :

- (a) estimated quantities and ultimate use of the controlled substance involved;
- (b) in the case of transit or export, the identification of destination countries or regions to which any such controlled substance will be held in transit or exported;
- (c) the commercial experience and integrity of operators and their staff, including their experience in dealing with the controlled substance; and
- (d) any other relevant matter that the PDEA may be prescribed from time to time.

Section 6. Requirements of Licenses and/or Permits for Operators or Handlers of Controlled Substance and Payment of Corresponding Fees

(1) No operator, except pursuant to and in accordance with the terms and conditions of a license granted by PDEA shall

- (a) cultivate any cannabis plant, coca bush, opium poppy, ephedra, or any plants from which dangerous drugs may be obtained;
- (b) manufacture, acquire or supply any controlled substance;
- (c) conduct research, laboratory analysis, training or other programs with the use of any controlled substance.

(2) No operator shall import, export, bring into the Philippines in transit, or redirect from the Philippines while in transit, any controlled substance and their preparations, except pursuant to and in accordance with any terms or conditions of:

(a) a license issued by the PDEA authorizing the applicant to carry out such activities in general; and

(b) a separate import permit, export permit, transit permit or redirection permit, authorizing the applicant to carry out the specific transaction the subject of the permit application.

(3) No medical practitioner shall prescribe a dangerous drug and/or its preparation in any dosage form, or drugs preparations containing controlled chemical without a valid S-2 license issued by the PDEA.

(4)(a)(i) Every transfer of dangerous drugs in any form and/or its preparation and raw material of Table I precursor chemical used in the manufacture of pharmaceutical drug preparation from one license holder to another or from one activity to another shall be made through an approved Local Order Permit as prescribed by PDEA. The application for a Local Order Permit shall include among others, the following information: date of application, supplier's name and address, particulars of the dangerous drug preparation to be purchased i.e. brand and generic name, dosage strength and form, packaging presentation, quantity ordered, and shall bear the full name and signature of the authorized pharmacist of the applicant entity, the complete address and current dangerous drugs license of the applicant entity indicating the validity . Maximum entry of five (5) dangerous drug preparations in an application form for single supplier. Such transaction shall have prior approval by the PDEA.

(ii) An approved Local Order Permit shall bear among others, the PDEA Permit number, date of issue and validity of the PDEA Permit, name , address and current PDEA license numbers with validity of applicant and seller, full name of the applicant's authorized pharmacist , particulars of the dangerous drug preparation to be purchased, i.e., brand and generic name, dosage strength and form, packaging presentation, quantity ordered, and the signatures of the authorized processing and approving PDEA-CS Officer.

(iii) An approved Local Order Permit comes in two (2) copies: Copy 1 for the seller/supplier; Copy 2 for the applicant purchaser.

(b)(i) A transporter/hauler/carrier of bulk controlled substance, which is not an integral unit of:

(1) a PDEA-licensed company to transact or deal in or manufacture controlled substance; or,

(2) a Customs Brokerage firm registered with the Bureau of Customs and/or Philippine Export Zone Authority; or,

(3) postal service, private or commercial courier service;

shall be required to obtain accreditation from PDEA to be authorized for such activity and pay an annual accreditation fee of five hundred pesos (Php 500.00).

(ii)The requirements for accreditation are as follows:

(1) Certificate of authorization to operate a trucking company and Mayor's Permit/Business Permit;

(2) Name and address of trucking company, owner and contact number;

(3) NBI clearance of owner or manager;

(4) Inventory of trucks indicating the make/form and plate numbers that will be used to transport controlled substances;

(5) Agreement Contract of contracting parties which shall include among others the provision of the security measures that will be undertaken to prevent diversion, losses/theft /pilferage during transport of controlled substance;

(6) Sworn Statement of Undertaking that transporter/hauler will strictly abide with the provisions of RA 9165 and other pertinent Rules and Regulations implemented by the PDEA, and in compliance with the Industrial Technology Development Institute (ITDI) of the Department of Science and Technology (DOST) ITDI/DOST Test Report on the calibration of tankers of all chemicals and other regulations for transporting controlled

substances. ITDI /DOST Calibration Test Report shall at all times be made available to PDEA when required; and

(7) Other relevant requirement/s as PDEA prescribes from time to time.

(5) Unless specified otherwise, the following groups of activities are deemed to be independent of each other and shall have separate registration and license:

- (a) prescribing;
- (b) dispensing/retail sale;
- (c) wholesale distributing;
- (d) importing, which includes wholesale distributing of what was imported only;
- (e) exporting;
- (f) manufacturing, which includes laboratory quality control analysis of controlled substance used in the manufacture of the controlled substance, and distribution of its own manufactured controlled substance;
- (g) end-using of controlled chemical;
- (h) recycling of controlled chemical, which includes wholesale distributing or retail of its own recycled controlled chemical;
- (i) storing or keeping in stock of controlled substance in separate address or addresses;
- (j) research or laboratory analysis or technical or teaching/training program; and
- (k) cultivation of plants from which a controlled substance may be obtained.

(6) An operator must secure from the PDEA as many licenses as he has places of business and/or activities. Any person conducting two or more types of business/activity at the same location shall secure from PDEA a license for each type of business/activity. For this purpose, PDEA shall issue a consolidated license detailing the type of license and corresponding authorized activity.

(7) An operator, after one year of operating as a license holder of good standing may secure a license to operate for up to three years, subject to recall or cancellation at any time, if any of the conditions set in the grant of the license by the PDEA or the provision of this Regulation is violated.

(8) Unless specifically exempted under this Regulation and other special laws or charters, the required fees per year for the corresponding licenses are as follow:

(a) Dangerous Drugs			
Item	Type of License	Description	Annual Fee
(i)	S-1 Retail distributor/ dispenser	License to sell, procure, acquire, deal in or with specified drug preparations, containing controlled chemical for retail, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].	P500.00
(ii)	S-2 Prescriber	License to prescribe (a) dangerous drugs preparation in any form; and/or (b) drug preparations containing controlled chemical, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].	P500.00 or P1,500.00 for three (3) years
(iii)	S-3 Retail distributor/ dispenser	License to sell, procure, acquire, deal in or with specified (a) dangerous drugs preparations in any form; or, (b) drug preparations containing	P1,000.00

		controlled chemical for retail, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]. Covers activities granted to S-1 License Holders.	
(iv)	S-4 Wholesale distributor	License to sell, procure, acquire, deal in or with specified (a) dangerous drugs and their preparations in any form; (b) drug preparations, containing controlled chemicals for wholesale distribution to license holders, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]; and (c) controlled chemicals used in the manufacture of drugs preparations The license holder need not obtain another license of the same nature of activity for such controlled chemicals.	P3,000.00
(v)	S-5-I Importer	License to import specified (a) dangerous drugs and their preparations in any form; (b) drug preparations containing controlled chemicals, except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]; (c) controlled chemicals used in the manufacture of drugs preparations; and, (d) in vitro diagnostic reagents, buffers and analytical standards, test kits containing dangerous drug. The license holder need not obtain another license of the same nature of activity for such controlled chemicals. May engage in wholesale distribution of that substance or class for which license was issued; may not distribute any substance or class for which not licensed].	P5,000.00
(vi)	S-5-C Manufacturer	License to manufacture specified (a) dangerous drugs and their preparations in any form; and (b) drug preparations containing controlled chemicals provided, that the license shall not apply to the compounding and filling of prescription in drugstores, clinics and hospitals. The license holder need not obtain another license of the same nature of activity for such controlled chemicals. May engage in wholesale distribution of that substance or class for which license was issued; may not distribute any substance or class for which it is not licensed. May conduct chemical analysis and quality control analysis with those substances for which license as a manufacturer was issued. May procure, acquire scientific apparatus or controlled laboratory equipment for manufacture of drugs. A controlled substances trader shall be categorized as a manufacturer.	P5,000.00
(vii)	S-5-E Exporter	License to export specified (a) dangerous drugs and their preparations in any form; and/or (b) drug preparation containing controlled chemicals : to foreign license holders.	P5,000.00
(viii)	S-5-D Bulk depot/storage	License for bulk depot/storage of specified dangerous drugs and their preparations in any form; (b) drug preparations containing controlled chemicals except drug preparation containing Norephedrine / Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].; (c) controlled chemicals used in the manufacture of	P5,000.00

		drug preparations; and when such address is separate and distinct from the office address of the license holder.	
b. Controlled Precursors and Essential Chemicals			
Item	Type of License	Description	Annual Fee
(i)	P-1 Retail distributor	License to sell, procure, acquire, dealing in or with specified controlled chemical or their mixtures or preparations, except drugs containing controlled chemicals, for retail sale.	P500.00
(ii)	P-3 End-User	End-user of specified controlled chemicals. NOT authorize to resell the controlled chemical. Authorized to purchase from local sources only	P2,500.00
(iii)	P-4 Wholesale distributor	License to sell, procure, acquire, dealing in or with specified controlled chemical except drugs containing controlled chemicals for wholesale distribution to license holders	P3,000.00
(iv)	P-5-I Importer	License to import specified controlled chemicals. May distribute that substance for which license was issued; may not distribute any substance for which not licensed].	P5,000.00
(v)	P-5-C Manufacturer	License to manufacture or recycle specified controlled chemicals or chemical mixtures excluding drugs containing controlled chemicals. May distribute that substance or class for which license was issued; may not distribute any substance or class for which not licensed. May conduct chemical analysis and quality control analysis with those substances for which license as a manufacturer was issued. May procure and acquire scientific apparatus or laboratory equipment for manufacture or recycling of chemical.	P5,000.00
(vii)	P-5-E Exporter	License to export specified controlled chemicals excluding drug preparations containing controlled chemicals	P5,000.00
(viii)	P-5-D Bulk depot/storage	License for bulk depot/storage the address is separate and distinct from the office address of the license holder.	P5,000.00
(ix)	P-5-IM Importer/End-user	License to import specified controlled chemicals, as End-user. Acquisition of controlled chemical shall be made through importation. The license holder is authorized also to acquire controlled chemical from local sources. Not authorized to resell the chemicals acquired.	P5,000.00
a. License to conduct laboratory analysis or technical research or instructional program or other programs			
Item	Type of License	Description	Annual fee
(i)	S -6 or P-6 Research/Analysis/ Instructional program	License to conduct laboratory analysis or technical research or instructional / training program, using controlled substances or drugs containing controlled chemicals or plant sources of controlled substances. May procure, acquire syringe, scientific apparatus or laboratory equipment	P500.00 per year

(9) All licensed operators shall use PDEA-prescribed forms for such activities but not limited to local order, importation, exportation or research/instructional/training program of controlled substances.

(10) PDEA license may be renewed within three months prior to expiration of license provided that the applicant is able to submit copy of documents as prescribed by PDEA including among others the Mayor's Permit/Business Permit issued by City/Municipal Government or PEZA Registration Certificate.

(a) Any change in the category of activity or change in ownership shall require a new license application.

(b) A surcharge equivalent to fifty percent (50%) of the required annual fee, cumulatively by year not paid shall be imposed for failure to renew the license within the period covered. Except in the case of an "S-2 License" which shall be PhP 500.00 per year.

(c) To avoid surcharges, licensee must notify PDEA in writing regarding its intention not to renew their license after expiration.

(11) The DDB shall upon legitimate request in writing by the concerned operator or party, issue Certification that a substance is included in the list of controlled substances. Such Certification shall be valid unless revoked due to non-inclusion of such substance in the list of dangerous drugs or controlled chemicals. A fee of P 300.00 shall be charged per Certification of ten (10) items. Exempted from payment of fees are national government agencies and government controlled or owned corporations and foreign counterpart regulatory or enforcement agencies.

(12) Substances not classified as dangerous drugs or controlled chemicals will not require Certification.

(13) Use of generic names of dangerous drugs and/or drug preparation containing controlled chemical,

(a) For practitioners- In issuing a prescription, a duly authorized practitioner shall indicate therein the generic name of the dangerous drug or drug preparation containing controlled chemical prescribed. The brand name may be included if so desired.

(b) Any operator involved in the manufacture, importation, exportation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels .

© For drug outlets – Drug outlets dispensing dangerous drugs and/or drug preparation containing controlled chemical shall practice generic dispensing upon consultation with the prescribing practitioner and shall not post in their establishment, a list of drug products using generic names with their brand names of dangerous drugs and / or drug preparations containing controlled chemical.

(14) Prohibition against advertising – Dangerous drugs or drug preparation containing controlled chemical shall not be advertised to the general public. It may, however, be advertised and promoted in medical journals, publications and literatures solely intended for medical and allied professions. Drug preparation containing Norephedrine / Phenylpropanolamine at doses of 25 mg or below which are classified as over-the-counter product are exempted from the prohibition against public advertising.

(15) Prohibition against distribution of samples – Dangerous drugs or drug preparation containing controlled chemical shall not be distributed as samples, except drug preparation containing Norephedrine / Phenylpropanolamine at doses of 25 mg or below.

(16) A licensed holder is not authorized to manufacture, import, export, end-use, transport, distribute or sell, dispense, administer a dangerous drug in the Philippine Schedule I unless for the purpose of a research program approved by the Board in conjunction with the Department of Science and Technology, the Department of Health, and Food and Drug Administration.

(17)(a) Where a group of hospital pharmacies comprising a central pharmacy and several smaller satellite pharmacies under a single management, the central hospital pharmacy may obtain a distributor's license for dangerous drugs and/or drug preparation containing controlled chemical and procure such drugs for distribution to the various satellite licensed hospital pharmacy through the local order permit system.

(b) Where an operator manages a nationwide pharmacy drugstore chain comprising a central pharmacy drugstore as main distribution point and subordinate regional central pharmacy drug stores, the central and subordinate regional central pharmacy drugstores may obtain license as wholesale distributors and procure dangerous drugs or drug preparation containing controlled chemical for distribution in the nationwide pharmacy retail drug store chain through the local order permit system .

(18) PDEA registered practitioner and dangerous drug operator are authorized to possess and use syringe and/or other instruments or equipment for the administration or use of dangerous drugs and / or drugs containing controlled chemicals for medical or dental or veterinary or research or laboratory purposes.

(19) An individual or person or website shall not make unauthorized use of the Internet, or causing the Internet to be used, to advertise the sale of, or to offer to sell, distribute, or dispense a dangerous drug and/or drug preparation containing controlled chemical without authorization from the Director General, PDEA.

(20)(a) A licensed operator may transfer mailable controlled substances to another licensee or ultimate consumer via postal service, private carrier or commercial carrier in accordance with a valid import, or export, or transit, or redirection permit or local order permit or prescription containing S-2 license of a medical practitioner, as the case may be. For domestic transaction in mailable controlled substance, the preparation for sending a shipment by courier service to the licensed buyer shall be under the supervision of an authorized supervisor of the licensed sender. The licensee is required to submit a monthly report of all such transactions regardless of the size of the transaction. The reports must include the name of the purchaser; the quantity and controlled substance purchased; the date of each transaction; the address to which the product was sent; and such other items of information which PDEA may require.

(b) The controlled substance together with the corresponding permit or prescription or clearance/certification must be placed in a box and double-wrapped with sturdy wrapper . The inner packaging of any mail piece containing a mailable dangerous drugs or drug preparation containing controlled chemical or controlled chemicals must be marked and sealed. The inner packaging must be securely held within a plain outer wrapper or packaging. No markings of any kind that indicate the nature of the contents may appear on the outside of the mail piece. The name, address and contact of both the sender and receiver shall be clearly printed on the parcel. The dispatch desk must ask for a valid identification of the sender from which a photocopy will be attached to the file document to the dispatching center.

(c) All packages delivered to the Postal Service mail carriers or by shipper/courier services, must have a shipping label attached and be permanently sealed so its contents cannot be removed. Packages containing dangerous drugs, processed for mailing or shipping, cannot have any annotation on its shipping label that identifies its contents. A carrier may possess a controlled substance or drug preparation containing controlled chemical in the course of such carriage from origin of dispatch to address of consignee.

(d) Regardless of any statement of any employee of the Philippine Postal Corporation or private or commercial courier service, the burden rests with the mailer to ensure that he or she has complied with the prescribed laws and regulations governing domestic and international mail/parcels, both those of the Philippines and those of the destination country.

(21) Dangerous drugs and/ or drugs containing controlled chemicals obtained through a prescription and intended for a specific patient cannot be sent to another person in a foreign country.

(22) Where a shipment of imported animals is accompanied by dangerous drugs for veterinary purposes, the importer shall make certain that the drugs are:

- (a) registered and/or approved by the FDA; and
- (b) the importer has licensed and an approved import permit from the PDEA.

Section 7. Application for Operator's License

(1) An original application of an "S" and "P" license or for the renewal thereof, shall be filed with the PDEA for the grant of a license and specify:

- (a) the full name, complete private and business address of the applicant;
- (b) each activity to which the application relates;
- (c) the full name and residential address of head of the establishment among others Chairman of the Board, President, Principal Executive Officer, General/Resident/Country /Plant/Area/Branch Manager, Partner, Owner/Proprietor, Medical Director, Hospital Administrator, Chief of Hospital who are/is responsible for the operation related to the controlled substance.
- (d) if the applicant proposes to engage in the activity under a business name, that name;
- (e) the specific controlled substance to which the application relates and its specific purpose of usage;
- (f) premises/place where the activity will be carried out and where controlled substance will be stored;
- (g) the security arrangements that would be implemented at each address, among others, storage, access, type of building construction, alarm systems, adequacy of supervision over employees having access, procedure for handling guests and maintenance personnel, adequacy of system for monitoring receipt, distribution and disposition of controlled substance;
- (h) the name, residential address and qualifications of each individual under whose supervision the activity would be carried out;
- (i) volume estimate in the current and forthcoming year, plus volume statistics for the past year of controlled substance needed; in the case of manufacture, the extraction, manufacturing and denaturing procedure to be used, name and quantities of the substances and raw materials to be used, estimates relating to each controlled substance produced, etc.; and
- (j) others as PDEA may prescribe from time to time.

(2) An application for license shall be accompanied by:

- (a) a plan of each of the relevant premises, indicating where the controlled substance would be stored, and the location and nature of any security devices;
- (b) License to Operate for Hospitals issued by the Department of Health or Food and Drug Administration's license to operate related to dangerous drugs and drug product registration, as applicable;
- (c) Registration from the Philippine Economic Zone Authority or Board of Investments or Bureau of Animal Industry, or PNP Supervisory Office for Security and Investigation Agencies (PNP SOSIA), as applicable;
- (d) Mayor's Permit/Business Permit issued by the Local Government Unit and Certificate of Business Name issued by the Department of Trade and Industry or Securities and Exchange Commission Registration or Cooperative Development Authority;
- (e) Current National Bureau of Investigation clearance for the head of the establishment and authorized signatory;

- (f) others as PDEA may prescribe from time to time; and
- (g) the prescribed fee.

Section 8. Grant of License

(1) Where an appropriate application has been made accordingly, PDEA may grant if satisfied that:

(a) The head of the establishment and authorized signatory :

(i) has no pending case or convictions involving provision of the Act or convictions involving any serious offense, or any offense however described relating to a controlled substance or other criminal offense including cruelty to animals; and

(ii) is otherwise a fit and proper person to hold a license;

(b) all places and premises at or in which the activity is to be undertaken are in fit and appropriate condition and with an appropriate signage in the place of business;

(c) the security arrangements and devices proposed at each relevant place and premises are appropriate and sufficient;

(d) the activity will at all times be carried out under the supervision of a person who is a fit and proper person to carry out that supervision;

(e) where the activity relates to a controlled substance, the activity will be carried out exclusively for legitimate purpose i.e. medical or scientific, or industrial purposes;

(f) the outcome of physical security inspection by PDEA Regulatory Compliance Officer is satisfactory.

(3) Grounds for denial of registration of license. An application for a license registration, may be denied by the PDEA upon a finding that the registrant/applicant:

(a) has materially falsified any application filed with the PDEA;

(b) has been indicted or convicted of a crime under any law of any country relating to any controlled substance or any other serious crimes, including cruelty to animals;

(c) has had his PDEA license registration previously suspended or revoked;

(d) has pending administrative or civil or criminal case against him/her;

(e) has been indicted or convicted of any crime involving moral turpitude;

(f) had committed any violations of any of the Rules and Regulation issued by the Board;

(g) has provided inadequate security for the storage of a controlled substance;

(h) has been engaged in spurious activities; and

(i) management/supervision of the business was not carried out by a fit and proper person.

(4) Procedure for denial of registration/license.

(a) PDEA shall within fifteen (15) working days after deliberation of the issue, render a decision to approve or not the application. The applicant shall be notified of the decision within five (5) working days after the decision is made.

(b) The applicant whose application is denied may seek reconsideration with the PDEA. Appeal maybe taken before the Dangerous Drugs Board Appeals Committee pursuant to Board Regulation No. 5 s. 2008.

Section 9. Contents and Conditions of Licenses

(1) A license issued by PDEA shall specify:

- (a) the full name and address of the licensee;
- (b) each activity to which the license relates;
- (c) the controlled substance to which the license relates;
- (d) the address of each place and premises at which:
 - (i) the licensed activity is to be carried out; and
 - (ii) the controlled substance is to be stored;
- (e) such terms and conditions as are necessary and reasonable for ensuring the proper:
 - (i) carrying out and supervision of the licensed activity;
 - (ii) establishment, maintenance and preservation of record relating to that activity;
 - (iii) reporting to the PDEA in relation to the carrying out of that activity;
 - (iv) maintenance and security of all places and premises at or in which the licensed activity will be carried out;
- (f) in the case of any license to import, export or bring to the Philippines in transit a controlled substance, the condition that a separate import, export or transit permit be first obtained in relation to any such transaction before it takes place; and
- (g) official receipt number of the payment of the prescribed fee.

Section 10. Applications for Import, Export or Transit Permits

(1) An application for an import, export or transit permit shall be made by a licensed operator to the PDEA at least fifteen (15) working days in advance before the transaction is to take place and specify the following:

- (a) the full name and address of the importer, exporter, carrier, consignee and, if known, of any ultimate consignee;
- (b) in the case of a proposed import, export or transit of a dangerous drug or its preparation:
 - (i) its international non-proprietary name or, its name as listed in the attached Annex of the Act, together with its trade name, if it has one; and
 - (ii) its pharmaceutical dosage form and strength;
- (c) in the case of a proposed import, export or transit of a controlled chemical or its mixtures, the name as specified in attached Annex of the Act and trade name, if it has one;
- (d) in the case of a proposed export of a controlled substance, the intended point of entry in the foreign State of intended import;
- (e) the quantity, mass, and volume or percent concentration in mixture of any controlled substance that is the subject of the proposed operation;
- (f) the date, or period within which, the planned import, export or transit is to take place;
- (g) the planned transport route, if known, including the planned point of entry or exit from the Philippines; and
- (h) in the case of a proposed import of a controlled substance to a bonded warehouse, the identity

and address of the warehouse.

(2) In the case of a proposed export of a dangerous drug, the import permit (by whatever name described) issued by the Government of the foreign State of intended import shall be attached to the application for export permit.

(3). A regulatory fee shall be paid for every application for permit for import, export, or redirection of controlled substances as follows:

(a) Five Hundred (Php 500.00) Pesos when the quantity of the controlled substance or their preparations is 1,000 kilograms or liters or less, as the case maybe;

(b) One Thousand (Php1,000.00) Pesos when the quantity of the controlled substance or their preparations is more than 1,000 kilograms or liters or less but less than 5,000 kilograms or liters, as the case maybe; and,

(c) One Thousand five hundred (Php1,500.00) Pesos when the quantity of the controlled substance or their preparations is 5,000 kilograms or liters or more, as the case maybe.

(4). Permits to be used for intended activities shall be as follows:

(a) for importation, transit and redirection of:

(i) a dangerous drug, an import permit shall be used; and

(ii) a controlled chemicals including its mixtures, a special import permit shall be utilized.

(b) for exportation, transit and redirection of a controlled substance, an export permit shall be used.

Section 11. Grant of Import, Export or Transit Permits

(1) The PDEA may, on application made by a registered or licensed importer or licensed exporter, grant an import permit, export permit, or transit permit in relation to a specified import or export transaction involving a controlled substance within a period of fifteen (15) working days, from the date on which the PDEA considers the file to be complete. This period shall be extended if, PDEA is obliged to make further inquiries in order to satisfy itself that the importation or exportation or transit shipment is proper.

(2) An approved import permit, export permit or transit permit is valid for a single shipment only.

(3) The PDEA shall not grant an export permit in relation to any shipment of a controlled substance to a bonded warehouse in a foreign State, unless the competent authority of that State has certified on the import permit that it has approved the import to a bonded warehouse.

(4) An import permit, export permit or transit permit shall specify:

(a) the full name and address of the registered or licensed operator granted it;

(b) the name (including any international non-proprietary name and trade name), quantity and form of any controlled substance for which it is granted;

(c) in the case of an import permit:

(i) the name and address of the exporter;

(ii) the import is to be effected in a single shipment ;

(iii) intended international port of entry in the Philippines

(d) in the case of an export permit:

(i) the name and address of the immediate consignee, and if known, of the ultimate consignee;

(ii) the number and date of any required import permit, from the foreign state, affirming that the import of the controlled substance, as the case may be, has been authorized by their respective country;

(iii) the intended port of entry in the foreign State of import;

(iv) if the export shipment is intended for an authorized bonded warehouse and is not prohibited, that the shipment is to be so exported;

(e) the period during which import or export is to be effected;

(f) in all cases of imports or exports of controlled chemicals, the Material Safety Data Sheet or Safety Data Sheet or latest version of the globally harmonized system-based (GHS-based) version of the controlled chemical should be submitted to PDEA and the Bureau of Customs.

(g) the case of an intended import to a bonded warehouse, a term that:

(i) any subsequent withdrawal from the bonded warehouse shall require a permit from the PDEA; and

(ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;

(h) such other particulars, terms and conditions as PDEA may consider operationally necessary and reasonable;

(5) Copies of approved import, export, transit or redirection permits shall be distributed as follows:

(a) one duly designated copy for the exporter/supplier or the consignee of the importing country, as applicable;

(b) two duly designated copies intended for the Commissioner of Customs or the Collector of Customs of the designated port of entry, one of which copies is to be retained by the operator for customs clearing purpose and other copy to serve as advance copy of the Bureau of Customs;

(c) one duly designated copy for the foreign counterpart competent authority of the country where the controlled substance is being imported or exported;

(d) one duly designated copy for the Philippine Embassy in the country where the import or export or transit or redirection will be made;

(e) one duly designated copy for the PDEA-CS file.

Section 12. Redirection Permits

(1) The PDEA may, on production by a licensed operator of a valid import authorization issued by an authority in the foreign State to which it is proposed to redirect a controlled substance, issue a redirection permit in respect of the controlled substance in transit. The licensed operator shall make an application in writing not later than fifteen (15) working days in advance before the transaction is to take place.

(2) A redirection permit shall specify:

(a) the full name and address of the registered or licensed operator granted it;

(b) the name (including any international non-proprietary name and trade name), quantity and form of any controlled substance for which it is granted;

(c) the name and address of the immediate consignee, and if known, of the ultimate consignee;

(d) the number and date of any required import permit affirming that the import of the controlled substance has been authorized;

- (e) the intended point of entry in the foreign State of import;
- (f) if the export shipment is intended for a authorized bonded warehouse and is not prohibited, that the shipment is to be so exported;
- (g) the period during which import or export is to be effected;
- (h) in the case of an intended import to a bonded warehouse, a term that:
 - (i) any subsequent withdrawal from the bonded warehouse shall require a permit from the PDEA and the Commissioner for Customs or Collector of Customs of the designated port of entry of the shipment; and
 - (ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;
 - (iii) such terms and conditions as the PDEA may consider necessary and reasonable.

(3) The PDEA shall not issue a redirection permit unless the PDEA is satisfied that the controlled substance is to be sent to the new country of destination in a lawful manner and for a legitimate purpose.

Section 13. Permits in Relation to First Aid Kits, Ambulances or Domestic or International Flights or Voyages , Medical Missions

- (1) The PDEA may, on written application made in the prescribed form by an applicant, grant a permit:
 - (a) to include a dangerous drug or drugs preparations containing controlled chemicals except drug preparation containing Norephedrine / Phenylpropanolamine at doses of 25 mg or below, in an emergency medical kit/bag/case or ship medical store for medical use during domestic or international flights or voyages or missions; or
 - (b)(i) for a foreign medical mission sponsored by any government agencies or other civic organizations to possess and supply reasonable quantities of dangerous drug or drugs preparations containing controlled chemicals needed during the missions, subject to prior import and/or export authorizations to be granted by the competent authorities of the foreign country where the medical mission or medicine originated and the Philippines; letter from head mission with the information on duration of mission and inclusive date, names and specialties of the mission team members, itemized list of the controlled drugs together with the expiration dates and flight or voyage details; DOH permit for subject mission; and deed of acceptance from the host hospital possessing a valid S3 license. Where the controlled medicines are to be supplied from the medical stores of the foreign uniformed service’s vessels operating under the mutual defense treaty or visiting forces agreement, the controlled medicines in possession and for supply by the concerned medical teams to patients during emergency situations not require import/export authorizations or permits provided that custody of the controlled substances are placed under the supervision of counterpart host’s field medical teams.
 - (ii). The Department of Health (DOH) shall be the lead agency in overseeing the implementation the conduct of foreign surgical and medical missions in the country and guided by the following:
 - (1) DOH Administrative Order Number 2007-0017 dated May 28, 2007 shall be the basis for acceptance and processing of foreign and local donations during emergencies and disaster situation; and
 - (2) DOH Administrative Order Number 54-A s. 2003 dated June 6, 2003 shall be the basis for the processing and clearance of importation through donations during normal situations by the Department of Health.
 - (iii)All dangerous drugs intended for use and donation during the mission, upon arrival, shall be placed under the custody of the partner host hospital or field pharmacy which possesses a valid

S3 license. Dispensation shall be through the required prescription forms. A post-mission report on use of the controlled drugs, signed by the pharmacist with the concurrence of the head of mission, shall be submitted to PDEA immediately upon culmination of the activity. Any remaining unused controlled drugs, except those that remain under the control of the foreign uniformed services' medical teams, shall not be returned to the country of origin but shall be retained by the pharmacy for post-mission disposition.

(2) A permit to include a dangerous drug and/or drug preparations containing controlled chemical except drug preparation containing Norephedrine / Phenylpropanolamine at doses of 25 mg or below shall specify:

- (a) the full name and address of the authorized person;
- (b) the name and maximum quantity of the dangerous drug and/or drugs containing controlled chemicals that may be procured or acquired;
- (c) such terms and conditions as are necessary and reasonable to ensure the proper use and safekeeping of the dangerous drug and/or drugs containing controlled chemicals; and
- (d) such other particulars as may be prescribed by PDEA.

Acquisition of emergency medical kits that are packaged with dangerous drug preparations shall be subject to the guidelines issued by PDEA (Annex E)

Section 14. Permits in relation to Laboratory Use and/or Programmes for Medical, and /or Scientific Research or Instructional/Training Purposes.

(1) The PDEA may, on written application made in the prescribed form, grant a permit to conduct medical and scientific research, laboratory analysis or instructional/training or other programs and purposes that would require the import, possession, cultivation or use of:

- (a) a dangerous drug;
- (b) a controlled chemical;
- (c) a plant source of a controlled substance;
- (d) a drug preparation containing a controlled chemical

(2) An application to conduct such a programme/activity shall specify:

- (a) the full name, address, academic, professional or other relevant qualifications of the applicant;
- (b) the controlled substance to which the permit is sought;
- (c) the strength and form in which the controlled substance to be used;
- (d) the maximum quantity of the controlled substance to be possessed at any one time, and the total quantity to be possessed during the laboratory analysis or period of the programme;
- (e) details of the manner in which the controlled substance is to be used;
- (f) the name and address of the place where the laboratory analysis or programme is to be conducted;
- (g) the name and academic, professional or other relevant qualifications of any person other than the applicant, under whose supervision and/or responsibility the programme would be conducted; and,
- (h) the security arrangements that would be undertaken while the controlled substance are cultivated or in possession, used or disposed of.

(3) An application to conduct such a medical or scientific research or laboratory analysis or instructional/training or other operational programs shall be accompanied by:

- (a) a written description of the programme, including its estimated duration;
- (b) in the case of a programme of research, a research protocol endorsed by a reputable organization;
- (c) in the case of a clinical trial, a clinical trial protocol endorsed by an appropriate agency/institutions.
- (d) in the case of instructional or training purpose, a program of instruction.
- (e) a written statement approving the conduct of laboratory analysis or programme, signed by the person-in-charge of the institution;
- (f) a National Bureau of Investigation clearance of the applicant(s); and,
- (g) prescribed fee, except for government agencies or exempted officials.

(4) The PDEA may authorize the use of controlled substances in the conduct of such medical or scientific research or laboratory analysis or instructional/training or any programme if satisfied that:

- (a) the conduct of laboratory analysis or programme cannot be carried out satisfactorily without the use of the specified dangerous drug or controlled chemical;
- (b) the programme is scientifically or medically viable having regard to any relevant protocol;
- (c) the applicant is a fit and proper person to conduct the laboratory analysis or programme;
- (d) the programme will be adequately supervised; and
- (e) the programme is to be conducted at, or under the auspices of, a recognized institution or government institution or acknowledged scientist or researcher or inventor.

(5) A permit shall specify:

- (a) the full name and address of the authorized person;
- (b) the controlled substance to which the permit relates;
- (c) the strength and form in which the controlled substance may be used;
- (d) the maximum quantity of the controlled substance that may be possessed or cultivated at any one time, and the total quantity that may be possessed or cultivated during the period of the programme;
- (e) the purpose for which the permit is granted;
- (f) the institution in relation to which the permit is granted;
- (g) such conditions as are necessary and reasonable for ensuring:
 - (i) the proper use and safe-keeping of the controlled substance; and
 - (ii) that proper records are kept concerning its receipt, use and disposal;
 - (iii) submission of periodic reports of the programme.
- (h) the condition that such reports as the PDEA may specify are sent to it on the use of the controlled substance in the programme, including particulars of the quantities acquired, used, disposed of and still held;
- (i) such other particulars as may be prescribed from time to time by the PDEA; and
- (j) official receipt of payment of prescribed fee (S-6 or P6)

Section 15. Permit in relation to International Transfer of Samples of Seized Controlled Substance

(1) The PDEA may, upon written request, grant an export permit for the authorized transfer of samples of seized controlled substance to the requesting government agency in foreign country for the purpose of drug profiling and international investigation.

(2) The request shall contain the following information:

(a) the full name and address of the immediate consignee and ultimate consignee;

(b) purpose of the transfer;

(c) the name (including any international non-proprietary name and trade name), quantity and form of any controlled substances;

(d) the number and date of any required import permit duly issued by the PDEA's counterpart competent authority in the country of destination, affirming that the import of the controlled substance has been authorized;

(e) the intended point of entry in the foreign State of import, specific mode of transport and the intended point of exit in the Philippines;

(f) the period during which export is to be effected;

(g) if the source of the sample of controlled substance is from evidence in a pending or on-going criminal case, copy of court order from the relevant Regional Trial Court, authorizing the taking of such samples;

(h) location of the seized controlled substance from which the sample would be taken.

(i) brief particulars of the criminal case.

Section 16. Extended Permit or Authorization for Related Activities.

Where a person is registered and licensed, or holds a permit or authorization in relation to any activity, the person shall, subject to the Act and this Regulation and to any terms or conditions of the license, permit or authorization, be deemed to be entitled to possess the relevant controlled substance for the purpose of that activity.

Section 17. Duration of Licenses, Permits and Authorizations

(1) A license, except for S-2 license as provided for by paragraph 3 hereof, shall remain in force for one (1) year for first time license holder and three (3) years for qualified renewal license holders, unless earlier surrendered, suspended or revoked, and may be successively renewed for a period of three (3) years by application in writing with corresponding requirements, signed by the applicant and accompanied by the prescribed fee. The applicant has the option to pay the full amount of fee for three (3) years or pay annually.

(2) A permit shall only remain in force for such period as may be specified in it, which in the case of an import for dangerous drugs or controlled chemicals and their preparations shall not exceed six (6) months, and in the case of export permit or transit permit for dangerous drugs or controlled chemicals and their preparations shall not exceed three (3) months and local order permit shall be valid for one (1) month from date of approval;

(3) An S-2 license shall remain in force for a period conforming with the validity of the licensee's registered Professional Regulation Commission (PRC) as indicated in the S-2 ID Card, unless earlier surrendered, suspended or revoked, and renewed for a period of three (3) years by application in writing with submission of the prescribed requirements, signed by the applicant and payment of the prescribed fee.

Section 18. Duty of Authorized Persons to Notify Material Changes, etc

(1) Where, in relation to any license or permit granted to any person, a material change occurs in the:

(a) Business name, or name or address of the person, or in the case of the establishment, the head of the establishment among others, Chairman of the Board, President, Principal executive officer, General/Resident/Area/Plant/Branch/Country Manager , or partner, owner, Medical Director, Hospital Administrator or Chief of Hospital or change of PDEA authorized pharmacist/signatory;

(b) address of the place or premises where:

(i) the licensed or permitted activity is carried out; or

(ii) any controlled substance stored;

(c) raw materials, or manufacturing or denaturing processes used in the licensed manufacture of any dangerous drug or drugs containing controlled chemicals;

(d) security arrangements implemented at any relevant address;

(e) identity of persons under whose supervision the licensed activity is carried out;

(f) planned transport route, including the planned date and point of entry or exit from the Philippines of any import, export or transit shipment which a permit has been granted;

(g) quantities of controlled substance arriving in relation to the approved import permit but not to exceed thirty percent (30%) of the total quantity approved, in such case the additional regulatory fee shall be paid;

(h) status of the planned importation of controlled substance; and

(i) Within five (5) working days of its occurrence or prior to the arrival of the shipment being imported, furnish the PDEA-CS with a written notice containing full particulars of the change, and shall return to the PDEA-CS the approved import/export permit or license.

(2) Retirement and Discontinuance of the License Granted

(a) A PDEA-licensed Operator or practitioner who intends to cease operation or prescribe dangerous drugs or its preparation and/ or drug preparations containing controlled chemicals on a specified date prior to or until the expiry date of the license shall notify the PDEA in writing at least sixty (60) working days in advance. PDEA-CS or PDEA Regional Office, as the case may be, shall conduct a pre-retirement compliance inspection. The operator shall and make arrangements for the legal transfer or sale of stocks of controlled substances to other operators until the termination of the license. Original copy of PDEA license, properly accomplished and updated record of transactions shall be submitted to the PDEA-CS or PDEA Regional Office within thirty (30) working days before the termination of the license. All controlled substances still held in stock shall be surrendered to PDEA Laboratory Service, or PDEA Regional Office on the expiry date of the license. Failure to surrender such stock of controlled substance will render the operator or practitioner liable for possession of dangerous drugs without authority and violation of Regulations. Approval of the retirement of license shall be through a written notification or via electronic mail.

(b) Failure to retire license upon expiration shall make the applicant liable to pay back account of the annual license/s not paid and surcharge of 50% per year except for S-2 license which is Php 500.00/year or a fraction thereof.

Section 19. Variation, Suspension or Revocation of License, Permit or Authorization

(1) If, at any time after the grant of a license, permit, registration or individual authorization, the PDEA may, as it deems necessary and reasonable in all the circumstances to prevent the risk of unlawful diversion:

(i) impose conditions, or vary any existing conditions specified in the license, permit or authorization, with effect within five (5) working days following the date of issue of a notice of variation;

(ii) suspend activities to sell or manufacture or import or export controlled substances;

(iii) suspend the license, permit or authorization for such period as PDEA deems necessary; or

(iv) revoke the license, permit or authorization.

If it appears that;

(a) license was granted on the basis of information that was false or misleading;

(b) a material change of circumstance has occurred since it was granted, whether notified or not;

(c) a condition to which an observed violation or findings, has not been complied with after being repeatedly notified in writing by the PDEA; or

(d) the person has a pending case or prior conviction of a drug law offense, or of other serious criminal offense, including cruelty to animals;

(e) registration and license had been previously suspended or revoked;

(f) licensee committed gross or repeated violations on any of the Rules and Regulations issued by the Board, including but not limited to the following:

(i) false and misleading entries in registers and records;

(ii) failure to maintain and keep records required for transactions on controlled substance;

(iii) prescribing not in accordance with existing Rules and Regulations;

(iv) dispensing not in accordance with existing Rules and Regulations;

(v) failure to notify loss, destruction or discrepancies in records;

(vi) failure to notify loss or theft of controlled substance;

(vii) unauthorized alteration on the nature of controlled substance in transit;

(viii) selling or acquiring controlled substance to or from an unlicensed operator;

(ix) selling controlled chemical with volatile solvent properties to a customer knowing that it will be used for abuse;

(x) importation, exportation of controlled substances without import or export permits, unless such controlled substances are specifically exempted from such permit requirement under this Regulation;

(xi) tampering of PDEA license or permit or prescription form;

(xii) operating an online pharmacy for dangerous drugs; and

(xiii) obstructing or hindering a PDEA Regulatory Compliance officer in the performance of his duties under this Regulations or an official PDEA investigation.

(g) the security provided for the storage of controlled substance is inadequate to the extent that repeated diversions by theft have occurred;

(h) the licensee has been convicted of a crime under any law of any country relating to any controlled substance or other serious offense

Suspension and revocation procedures shall follow PDEA prescribed guidelines. (Annex F)

(2) Any person whose license, permit or authorization is suspended or revoked after due proceedings shall return it to the PDEA-CS or through PDEA Regional Office not later than five (5) working days after the PDEA notified the person in writing of the revocation or suspension. No transactions on the controlled substance handled shall be conducted in such case.

(3) No establishment whose license was revoked may apply for a license five (5) years after the revocation of its license.

Section 20. Duty of Operators to Check and Notify Suspicious Orders and Transactions

Whenever a licensed-operator has reasonable grounds to suspect that the information that it has concerning the order or transaction, may be relevant to an offense or a possible offense against the Act, the operator shall, immediately communicate to the PDEA-CS or PDEA Regional Office, after establishing that suspicion, particulars of the suspicion, the basis for it, and such other information, if requested, as the person has in relation to the order or transaction.

Section 21. Prohibition from Dealing with Unlicensed Operators

(1) No licensed-operator shall sell to or acquire from another operator in the Philippines any controlled substance and their preparations unless the second operator is also licensed and in the case of dangerous drugs and/or drug preparation containing controlled chemicals pursuant to a Local Order Permit duly approved by the PDEA.

(2) A licensed retail seller/handler of controlled chemical may sell a controlled chemical in a quantity not exceeding the prescribed total weight/volume in a single transaction or multiple transactions in one month to a regular or known customer without the latter presenting a license, as follows:

Single Component Chemical	Total
Acetone	5 liter
Hydrochloric Acid	25 liters
Sulfuric	25 liters
Ethyl ether	5 liter
Toluene	5 liter
Methyl ethyl ketone	5 liter
Potassium Permanganate (for medical purposes)	100 grams

(3) In application of Section 21(2):

(a) transactions shall be made for the legitimate use by the purchaser and not to be resold by the purchaser;

(b) the licensed seller shall not sell any controlled chemical in whatever form or any quantity to a customer who is less than eighteen (18) years old without the written consent of his/her parents or guardian, or knowing that the buyer will sell or give it to a person who is less than eighteen (18) years old for the purpose of abuse;

(c) ask the customer for any valid identification/document such as driver’s license or passport or office or voter’s or senior citizen’s or Philhealth or Postal Identification or company/student’s card, and signature not the customer;

(d) An operator must exert every means possible to identify the party to the transaction. The operator must verify the existence and validity of an entity ordering the controlled substance and maintain a customer file or an end-user declaration signed and dated by the person acquiring the controlled chemical.

(i) The end-user declaration shall include among others the following:

(1) the name of the person acquiring the controlled chemical, or in the case of a corporation, its corporate name, as well as their address and telephone number

and facsimile transmission number, if any;

(2) the name and quantity of all controlled chemicals involved in the transaction;

(3) all uses for which the controlled chemical is being acquired; and

(ii) An end-use declaration applies to any subsequent transaction between the licensed dealer and the signatory to the declaration that occurs in the same calendar year as the transaction mentioned in the declaration if the subsequent transaction involves the same controlled chemical and the same end-usage.

(iii) Another end-user declaration shall be obtained in respect of a subsequent transaction between the licensed dealer and the signatory to the declaration that occurs in the same calendar year as the transaction mentioned in the declaration if the transaction involves a different controlled chemical or a different end-use.

(iv) A licensed dealer required to obtain an end-user declaration shall take reasonable steps to verify the identity of the signatory to the declaration if that person or their signature is unfamiliar to the licensed dealer.

(v) For uniformity, an end user declaration template format in Annex G shall be used for the purpose.

(e) A transaction shall be recorded by the licensed seller in a register, and subject to inspection at any reasonable time by a PDEA Regulatory Compliance Officer.

Section 22. Controlled Substance in Lawful Transit

(1) No person shall cause a controlled substance lawfully in transit to be subjected to any process which could alter its nature; or otherwise than in accordance with instructions issued by the PDEA, willfully open or break any package or container containing any controlled substance in transit.

(2) No licensed operator shall, except under the authority of a duly redirection permit, cause or procure any controlled substance, in transit to be redirected to any destination other than that shown on the export permit or redirection permit accompanying the drug or chemical.

Section 23. Commercial Documents

(1) Any commercial document, such as an invoice, cargo manifest or a customs, transport and other shipping document, relating to any transaction by an operator involving a controlled substance shall include:

(a) the name and quantity of the controlled substance;

(b) in the case of any import or export, the name and address of the exporter, the importer the consignee, origin of the controlled substance, port of embarkation, port of debarkation, registered name of the conveyor, date of departure from origin, date of arrival and port of entry.

Section 24. Forwarding of Import Permit in advance to Proposed Foreign Exporter

Where the PDEA issues an import permit to an operator, the operator shall forward the permit to the exporter named in the permit not later than five (5) working days.

Section 25. Export Permits to be Attached to Shipments

Where the PDEA issues an export permit to an operator, the operator shall attach an authenticated copy of the permit to each shipment on export.

Section 26. Notification, Endorsement and Return of Export Permits following Import

(1) After an imported shipment of controlled substance has entered Philippines or when the period stipulated in the import permit expires:

(a) the licensed operator granted the permit should immediately report (first notice) to the PDEA-CS or PDEA Regional Office, as the case may be the arrival of the subject shipment at the designated port of entry;

(b) In case the total quantity of the shipment is more than **30%** of the approved quantity in the import permit, and the import permit does not specifically provide for such occurrence, the

shipment shall be subject to seizure proceedings by the Bureau of Customs under applicable laws, Rules and Regulations.

(3) After the shipment is cleared from Customs, the importer must also report (Second Notice) immediately the date of arrival of the shipment at the operator's licensed depot or storage facility for immediate inspection or An Accredited Custom's Broker or transporter/carrier shall, when transporting an imported controlled substance between the port of entry and the site set out in the permit/license, or when sending, delivering or transporting a controlled substance to a destination, including the port of exit, take all steps necessary to ensure the safekeeping of the controlled substance during transportation or ensure that all steps are taken so as to prevent the diversion of the controlled substance to an illicit market or use.

(4) (a) the Commissioner of Customs or his duly authorized representative at the duly designated port of entry shall endorse the Customs copy of the import permit, to the PDEA, confirming the date and mode of arrival of the shipment, within the first ten (10) working days following its importation;

(b) If the shipment did not arrive within the period specified in an import permit, the Commissioner of Customs or the Collector of Customs of the designated port of entry shall endorse the expired import permit to the PDEA with notation that the shipment did not arrive, within ten (10) working days following the expiry date. Likewise, the importer must also notify the PDEA-CS or PDEA Regional Office as the case may be.

Section 27. Forwarding of Redirection Permits

(1) Where a redirection permit is duly issued:

(a) one copy shall accompany the controlled substance when it is exported from the Philippines;

(b) the PDEA shall cause another copy of the redirection permit to be sent forthwith, upon issue to the authority in the foreign country to which the shipment has been redirected;

(c) one copy shall be retained by the operator;

(d) one copy shall be provided to the Collector of Customs of the port of entry/exit; and

(e) one copy to be retained by the PDEA-CS for file.

(2) Upon the issuance of a redirection permit, any person holding the export permit or redirection permit accompanying the drug or chemical on its arrival in the Philippines shall remit it to the PDEA who shall return it to the competent authority issuing it, together with:

(a) notice of the name of the foreign country to which the shipment has been redirected; and,

(b) an endorsement specifying the quantity of each controlled substance, actually imported.

Section 28. Liability to Forfeiture of Improperly or Undocumented Shipment

(1) A shipment of a controlled substance is liable to forfeiture if:

(a) even though it is accompanied by an export/import permit or redirection permit, there are reasonable grounds to believe that the permit is false, or has been obtained by fraud or willful misrepresentation of a particular material;

(b) there are reasonable grounds to believe that any import permit relating to it is false;

(c) in the case of a shipment of a dangerous drugs , it is not accompanied by any export/import or redirection permit;

(d) in case of a shipment of controlled chemical, the condition of the license is grossly violated in relation to Section 19 of this Regulation; and

(e) undeclared or misdeclared shipment of controlled substance.

Section 29. Limitation of Licensee's Stocks

(1) On or before 31 December each year, the DDB, in consultation with concerned agencies and stakeholders shall, in the light of the prevailing market conditions, and the estimates submitted to and approved by the International Narcotics Control Board, determine the maximum quantities, of each controlled substance that may be manufactured or held in stock for the normal conduct of business during the following year.

(2) When the need arises, the Board may, at any time amend, any such determined quota, and shall promptly notify PDEA in writing of the amended quota.

Section 30. Persons Authorized to Engage in Professional Supply of Dangerous Drugs or Drugs containing Controlled Chemicals

(1) No person shall engage in conduct that constitutes professional supply of any dangerous drug or drug preparations containing controlled chemical, in any dosage form, which require valid S-2 license, except:

- (a) a pharmacist, acting in accordance with the norms and standards of the pharmacy profession, who supplies to another person on prescription or on requisition, in the ordinary course of a pharmacy business;
- (b) a licensed practitioner, provided that such supply at all times takes place under the immediate supervision of a pharmacist;
- (c) a medical practitioner who, in accordance with the norms and standards of his or her profession:
 - (i) administers the drug directly to a patient or animal in the ordinary course of treatment; or
 - (ii) supplies the drug to a patient or for an animal in the ordinary course of treatment from a place more than five (5) kilometer-radius from the place of business of a pharmacy or within five (5) kilometer-radius where there is no pharmacy store dispensing dangerous drugs and/or drug preparations containing controlled substances.

Section 31. Prescriptions

(1) No person shall prescribe a dangerous drug or drug preparation, in any dosage form, which require a valid S-2 license, unless that person is a medical practitioner ;

- (a) who prescribes the drug in the ordinary practice of their respective profession
 - Physician
 - Dentist
 - Veterinarian

(b) granted an S-2 license to prescribe such drugs by the PDEA.

(2) A prescription for a dangerous drug shall

(a) be on a Special Prescription Form unless specifically exempted ;

(b) be signed and dated by the prescribing practitioner on the date of issue;

© contain only one dangerous drug and/or drug preparation containing controlled chemical;

(d) issued in triplicate copies with specific direction of use. The original copy of prescription (specifically marked as the original copy on the face of the prescription) shall be surrendered to the drugstore or pharmacy which dispensed the drug, the duplicate copy (specifically marked as duplicate copy on the face of the prescription) will be a copy of the patient or purchaser-representative, and the triplicate copy (specifically marked as triplicate copy on the face of the

prescription) will be retained by the prescribing practitioner;

(e) if the prescription is issued by a veterinarian, the following information should be indicated;

- (i) the inscription "for animal use" on the face of the prescription;
- (ii) the name, address and contact numbers of the owner or caretaker of the animal. The name and address of the person who will receive the drug if not already detailed earlier, shall also be handwritten;
- (iii) the species of animal;
- (iv) a means of identifying the animal, such as electronic chips, tattoos, ear tags, name tags/collar, and other identifying marks;
- (v) Address of the premises where the animal is kept, if different to that above;
- (vi) The total quantity of medication in words and figures in the hand writing of the person prescribing the medication, including the dosage strength and number of dosage units;
- (vii) administration instructions and any relevant warnings. Indicate gradual reduction of medication;
- (viii) Diagnosis of the veterinarian signing the prescription; and
- (ix) In the case of a prescription for dangerous drug in parenteral form which is directed to be administered more than once, the time interval between repeat administering.

(4) The standard information to be supplied in the prescription shall be: the full name, complete business address, telephone number/email address, current S-2 License number and validity of license, and Professional Tax Receipt of the prescribing practitioner; complete name, age, and complete address of the patient, date of the prescription, generic and brand name of the preparation to be supplied, its dosage strength and form and the total number of dose units or total quantity of preparation to be supplied **in words and its numerical equivalent**; direction of use, and the inscription "no refill" at the face of the prescription, and the original signature of the medical practitioner. Direction of use must be specified. "Take as directed" or "Take as required" is not authorized

(5)(a) No prescription once filled by the drugstore or pharmacy shall be refilled.

(b) Whenever a prescription for dangerous drugs is filled by the drugstore, it shall be the duty of the drugstore owner/pharmacist to cause the inscription "USED IN FULL" to be stamped in bold prints across the original copy of said prescription in case the full quantity of the drug therein stated is sold or dispensed, and the inscription "USED FOR (dosage/units) ONLY" in case the quantity of the drug quantity of the drug therein stated is not fully dispensed." The balance should be clearly indicated at the face of the prescription **in words and its numerical equivalent and signed by the dispensing pharmacist**. The pharmacist shall not reduce the quantity specified in the prescription unless by reason of lack of stock of the drug or the prescription holder asks for the reduction in quantity due to budgetary constraint. The dispensing pharmacist shall affix his/her signature at the face of the prescription and shall be made accountable for any violation that may be committed.

(c) The pharmacist shall follow the order and instruction of the physician as written on the prescription unless the pharmacist has sufficient reason to question the validity of the prescription, in which case the pharmacist shall contact the prescribing practitioner for verification.

(d) A pharmacist shall not supply a dangerous drug and/or drug preparation containing controlled chemical on presentation of a prescription, if she/he knows or has reason to believe that the prescription or order is:

(i) forged, unlawfully altered, or cancelled; in which case the pharmacist shall contact the prescribing practitioner for verification.

(ii) issued more than sixty (60) days before presentation, except that for multi-months prescription, the sixty (60) days shall be based on the date indicated by the practitioner when **the drug shall have been obtained**;

(iii) already terminated by the discontinuance of the medication by the prescriber or death of the patient;

(iv) the prescription is outside the scope of practice of the prescriber;

(v) not complete, legible, properly prepared, properly signed, or shows any signs of alteration or erasure.

(e) The dispensing pharmacist shall require the person who will receive the drug to indicate his/her complete name, and address, valid identification card with picture **(to be photocopied for reference/file)** and affix signature at the back of the prescription.

(6)(a) A PDEA licensed practitioner shall prescribe only FDA-registered dangerous drug for patient use in any medically needed and reasonable quantity that is determined by documented clinical need or recommended in the Philippine National Formulary (PNF), Physician Desk Reference, Medical or Veterinary Books or in the usual dosage as set forth in published professional medical or veterinary references. Where the responsible prescribing practitioner has evaluated the patient's condition and determined that there is a need for a longer duration of therapy, the practitioner may prescribe for a period not to exceed thirty (30) days supply per prescription, except under extraordinary circumstances. The prescribing practitioner shall indicate a specific length of therapy or number of doses in the individual patient's order, as in long-term care, hospice and oncology patients.

(b) Prescribing and dispensing of parenteral form of dangerous drugs shall be for administration to patients in PDEA licensed hospitals and other institutions authorized by the Department of Health as institutional dispensers under their care, or in temporary field hospitals during emergency situation, or in homes where the patient has attending physician and nurse.

(c) A prescription is valid when it is issued for a legitimate medical purpose in the usual course of professional practice by a PDEA licensed practitioner. A practitioner shall not prescribe, administer, or otherwise provide, or cause to be provided any dangerous drug to a person who the practitioner has never personally physically examined and diagnosed except in institutional settings and on-call situations.

(d) A PDEA licensed practitioner may prescribe dangerous drug for patient use for up to thirty (30)-day supply of Philippine Schedules 2, 3, and 4 dangerous drugs per prescription.

(i) In extraordinary circumstances, where the prescriber:

(1) considers more than thirty (30) days is clinically indicated, the prescribing physician may issue multi-month prescriptions, not exceeding thirty (30) days supply per prescription or a total of ninety (90) days supply for drugs in Schedule IV of the 1971 UN Convention, all dated on the day of issue and with written instructions on the second prescription of when to obtain the medicine. In such cases, the prescriber shall indicate on the face of the prescription, the number of prescriptions issued to the patient i.e. one of 3 Rx, two of 3Rx and three of 3 Rx; **and**

(2) after having made a prescription for thirty (30) days supply and the condition of the patient, has required more dose medication than originally assessed, the prescribing physician may issue a supplemental prescription within the thirty day period when the original prescription was made.

Provided, that it would not pose an unacceptable risk to patient safety, a record of the reasons for deviating from the guidance should be made in the patient's medical record, regular periodic check-up of the patient should be made.

(e) A practitioner may prescribed a sixty (60) days supply of **Philippine Schedule 4 drugs for the treatment of epilepsy and dystonia.**

(f) Dangerous drugs covered under Philippine Schedule V are to be prescribed as necessary.

(g) A prescription shall not be issued in order for an individual PDEA licensed practitioner to obtain

controlled substances for the purpose of general dispensing/selling to his/her patient or for his own use.

- (7) Medicines prescribed for an individual patient must be supplied to, and used by that patient only. A medical practitioner must not use patient-specific dangerous drug prescriptions to replace or 'top-up' their bags for home visits even if the stock was used for that patient initially.

(8) Medical practitioner planning treatment options of a patient who has pain from cancer, or intractable pain, or pain as a result of terminal illness, or, any ailment requiring dangerous drug preparation, shall ensure that a patient's medical history has been obtained and a physical examination has been conducted, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of drug abuse, and the nature, frequency, and severity of any pain. **The practitioner shall document the diagnosis and the medical need for the prescription in the patient's medical record.** The medical record must reflect:

- (i) a recognized medical indication for the use of the dangerous drugs;
- (ii) generic and brand name of the dangerous drugs
- (iii) the dosage, strength, and quantity of the dangerous drugs;
- (iv) specific instructions to the patient about frequency of use; and
- (v) patient response to the treatment

A practitioner shall remain alert to the possibility that dangerous drug may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning dangerous drug use and consequences for misuse.

(9)(a) A prescription shall not be issued for the dispensing of dangerous drugs and/or drug preparations containing controlled chemicals to a drug dependent person for the purpose of continuing his dependence upon such drugs.

(b) Unless the practitioner is properly registered by the DOH to conduct a treatment program, a practitioner shall not prescribe or administer a dangerous drug if that drug is intended for "detoxification" or "maintenance treatment," except:

(i) To relieve acute withdrawal symptoms, provided that:

- (1) Such treatment does not exceed seventy two (72) hours;
- (2) Not more than (one) 1-day's supply of the drug is provided to the patient at a time; and
- (3) Arrangements are made for referring the patient to a drug treatment program for treatment.

(ii) As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility."

(10)(a) In consonance with Section 30(1)(c)(i)(ii), a physician may store in his/her clinic or carry in his medical carry/emergency bag a reasonable quantity of such drugs, including, paraphernalia for administering the drug to a patient. Acquisition of the dangerous drug in reasonable quantities shall be on patient-based-actual-monthly-consumption and mode of resupply, and shall be through an approved local order permit. He/She shall maintain record of receipts and disposal in a register and submit semi-annual report of transaction to PDEA.

(b) An individual PDEA licensed practitioner that holds stocks of dangerous drugs should keep stock levels to a minimum but keep enough to meet clinical need. The stock level held in emergency bag should also be kept to a minimum as dictated by previous requirements. Only a single strength of each controlled drug shall be kept in the bag. Oral preparations of dangerous drugs should not routinely be carried in the emergency bag. PDEA shall issue guidelines on the dangerous drug or drug preparations containing controlled chemical content of the emergency bag.

(c) A PDEA licensed practitioner must ensure that all dangerous drugs under his/her control are kept in a locked container, which is constructed and maintained to prevent unauthorized access to the drugs and can only be opened by the licensed practitioner.

(11) Acquisition of dangerous drugs for compassionate reason:

(a) Where a dangerous drugs that is:

- (i) FDA-registered in the Philippines but not available;
- (ii) duly registered as a medicine in a source foreign country but not in the Philippines;
- (iii) needed for treatment by a patient; and
- (iv) without any available drug substitute,

the PDEA S-2 licensed practitioner and the patient or owner of the patient-animal shall jointly request the FDA for a compassionate permit.

(b) FDA shall endorse the Compassionate Permit to PDEA which in turn will endorse it to a license importer/distributor of dangerous drugs for necessary importation process.

(c) The attending PDEA licensed practitioner will obtain the drug from the distributor through an approved local order permit.

(d) The patient shall be responsible to the importer/distributor for the cost of importation.

(e) The PDEA licensed practitioner shall keep the drug in a secure location as prescribed in Section 31(10)(c) and record the use of the drug in a register as prescribed in Section 37 of this Regulation. He/she shall submit semi-annual report of transaction to the PDEA. In cases, when the medication drug is no longer needed by the patient, it shall be immediately surrendered by the practitioner or the patient or a family member of the patient to the PDEA for proper disposition.

(12)(a) Veterinary practitioner may only prescribe or dispense a dangerous drug for veterinary or animal use:

(i) after having actually examined the animal, established the therapeutic need and documented the clinical justification of the need in the veterinary medical record:

(ii) in the usual dosage determined by documented clinical need or as set forth in published veterinary references;

(b) An animal or herd is considered to be under the veterinary practitioner's care, under the conditions:

(i) a valid veterinarian-client-patient relationship exists. The owner or the owner's agent gave the veterinarian responsibility for the health of the animal or herd in question; and

(ii) the veterinary practitioner has personal contact with the animal/herd for diagnosis and treatment and assumed responsibility for the diagnosis, treatment and outcome and the practitioner has a thorough knowledge of the current health and treatment status of the animal or herd.

(c) Hospitalized animals may be prescribed dangerous drugs. Dangerous drugs obtained from secured storage area shall be recorded, as well as the patient information (owner's complete name, animal name, identification number) and initials of the person withdrawing the medication. For parenteral medication, the syringe and needle shall be properly discarded after the drug is administered. Dangerous drugs cannot be administered from the hospital unless the veterinarian prescribing the drug is physically present.

(13)(a)(i) A physician, dentist, veterinarian or other practitioner possessing a valid PDEA S-2 license can purchase at most ten (10) booklets of special prescription form for dangerous drugs at a time from the DOH or its official distribution sites.

(ii) Purchase of new special prescription form for dangerous drugs will be done when a balance of ten (10) unused prescription forms remain.

(b) Special Prescription Form for dangerous drugs issued to a physician, veterinarian, or dentist, possessing a valid PDEA S-2 license is non-transferrable and accountable forms. It shall be for the exclusive use of physician, veterinarian or dentist to whom such forms are issued and shall be used consecutively.

(c) All unused Special Prescription Form for dangerous drugs shall be immediately surrendered to DOH or its official distribution sites under any of the following circumstances:

(i) departure for any place outside the Philippines, if the period of stay therein is more than six months;

(ii) cessation of, or retirement from, practice;

(iii) non-renewal of PDEA S-2 license;

(iv) death – Surrender of the special prescription form for dangerous drugs may be done by the nearest kin of the deceased practitioner to whom such forms were issued; and

(v) in any case, the DOH or its authorized representatives shall issue an acknowledgment receipt for the surrendered special prescription forms for dangerous drugs.

(d) The licensed practitioner shall keep the used prescriptions booklets in a separate file in such manner as to be readily accessible to inspection by PDEA, for a period of one year.

Section 32. Requisitions, Dispensing and Administration in Hospitals/Institutions for Purpose of Treatment

(1) No person shall issue a requisition for a dangerous drug and/or drug preparations containing controlled chemical which require S2, unless the person is:

(a) a PDEA-licensed pharmacist in a hospital/institution; or

(b) PDEA licensed medical practitioner in-charge of the ward/unit/pavilion/department in a hospital/institution.

(2) Only an authorized pharmacist can issue a supply of dangerous drug and/or drug preparations containing controlled chemical which require S2 to ward or clinic at a hospital/institution for the treatment of a patient therein.

(3) A requisition for such drug **in hospital or related setting** shall:

(a) be legible;

(b) specify the complete name of the person issuing it and the capacity in which he or she issues it;

(c) specify the name, quantity, form and strength of the drug;

(d) specify the ward or dispensary where the drug is required;

(e) be originally signed and dated by the **nurse-in-charge** and PDEA licensed medical practitioner in-charge of the unit /ward/**pavilion/department**; and

(f) **be countersigned by the pharmacist** who is to supply the dangerous drug and/or drug preparation containing controlled chemical which **requires S2 license**.

(g) A copy of the specimen signature of each authorized practitioner shall be kept and made available in the hospital pharmacy department for validation. A sample signature page should be maintained in the inside cover of each requisition book. Where electronic systems are in place, there should be a validated identity of individual signature who requisitioned the dangerous drugs by means of authorized computers officially assigned to the unit/ward/pavilion/department for the purpose. The prescribing practitioner shall provide a duly notarized legal document that he/she is accountable of all prescriptions issued/made electronically bearing his/her electronic

signature. It shall be the duty of the authorized pharmacist of the hospital to keep the said document on file which shall be made available to PDEA when required.

(h) Stock levels shall be periodically assessed prior to ordering. The ward/unit/pavilion/department dangerous drug stock list shall reflect current patterns of dangerous drug's usage by said units.

(4) High strength opiate/narcotic which applies to any single ampoule or vial of injection, that is equal to or greater than 30mg must only be ordered when required to meet an individual patient's needs.

When ordering high strength opiates/narcotic drug, the requisition will be accompanied by a copy of the named patient Prescription and Medication Administration Record.

(5) Hospitals/institutions may, for its own purposes, use any drug distribution system such as individual prescription or electronic medication order system or complete floor stock system or decentralized pharmacy under the direct supervision of a pharmacist, unit dose method, and combination of prescription order system, complete floor stock system and unit dose system for dispensing drugs for in-patients.

(a) Drug dispensing and administration

(i) Orders for controlled drug to be administered to patients from unit dose or ward/department/unit/pavilion stock must be written for periods not to exceed one (1) day.

(ii) In general, a daily controlled drug administration sheet shall be maintained for dangerous drug and/or drug preparation containing controlled chemical issuance for floor stock to specialized **departments or units** or ward or pavilion. The required information on the daily controlled drug administration sheet are as follows:

- (1) Date and time of administration
- (2) Patient's full name, hospital I.D. number, room/bed number
- (3) Name of prescribing physician, S-2 License Number and signature
- (4) Name of administering nurse, PRC License Number and signature
- (5) Dose administered
- (6) Inventory column
- (7) Remarks (ex. quantity of unused portion discarded, emergency case/verbal order, out-of-stock procured from other pharmacy outside the hospital).

The prescribing practitioner and the administering nurse shall certify as to the correctness of the information entered and affix their respective signatures in the controlled drug administration sheet which shall be submitted to the hospital pharmacy upon full consumption of the dispensed dangerous drug in the order.

(iii) Administration of parenteral dangerous drugs to patients should be performed by at least one registered nurse and witnessed by a competent other. Administration of dangerous drugs to patients should be in response to an original valid written order in the possession of the administering nurse.

(iv) Order to the nurse on duty by the attending PDEA-S2 licensed physician for the administration of dangerous drugs shall always be in writing unless in emergency situation. In such cases, the written order shall be endorsed by the prescribing physician following administration with the word "ADMINISTERED", nature of emergency situation and then date it.

(v) Administration of the dangerous drugs to a patient should be done in the presence of a witness. For oral dangerous drug the patient should be observed swallowing the medication.

(vi) The administration process should be fully completed for each patient before moving on to the next patient. Dangerous drugs must not be lent or borrowed between departments/units/wards. They should only be removed from the dangerous drugs secured storage or medical cart for the immediate administration to a patient for whom the medicine is prescribed.

(vii) In ordering and administering drugs to patients, the metric system should be used

exclusively in ordering drugs; and

(viii) Dangerous drugs must not be lent or borrowed between ward/department/unit/pavilion and should only be removed from the controlled drug's cupboard for the immediate administration to a patient for whom the medicine is prescribed, who may be on the ward.

(b) When an in-house prescription for dangerous drugs is not available in the hospital pharmacy, and the drug is procured from other pharmacy outside the hospital, the drug shall be turned over to the hospital ward nurse in-charge for the purpose of safekeeping and recording of administration in patient's clinical chart.

(6.) PDEA-Prescribed forms to be used are as follows which shall be made available for monitoring purposes:

(a) Requisition Sheet

(b) Controlled Drug Administration Sheet
Refer to Annex H.

Section 33. Prescribing and Filing of an Order in Emergency Situation

(1) (a) Where the need for treatment is urgent in an emergency case, an ordinary prescription not in special prescription form for dangerous drugs may be given, and shall be acted upon by the licensed seller. **An "Authorization for Emergency Dispensing," must be legibly written on the face of the prescription. The drug prescribed and dispensed must be limited to the quantity needed to treat the patient during the emergency period.** The prescribing physician, dentist or veterinarian shall inform PDEA where the emergency occurred, **in writing copy furnish the pharmacy** that supplied the drug in writing within seven days (7) after issuing such ordinary prescription. **The pharmacy shall also inform the PDEA within seven (7) days after dispensing the dangerous drugs during the emergency situation.** Such prescription should contain at the back of it statement of date and nature of emergency condition. The prescription should clearly state the full name and address of the patient, and the full name and signature of the prescribing person **and such other information required under Section 31(4) of this regulation. The notification to PDEA may be delivered in person or by mail. But if delivered by mail, it must be postmarked within the seven day period.**

(b) In hospital setting, telephone or verbal orders may be taken only when the life of a patient would be jeopardized by failure to take immediate action, and are applicable only to orders given by the medical practitioner in the presence of an authorized health care professional (registered nurse, pharmacist, or respiratory therapist). The order shall be recorded on a medical practitioner order form in the patient's medical chart. The health care professional receiving the order shall sign her name in behalf of the name of the prescribing practitioner and indicate the time at which the order was received. Such oral order shall be signed by the prescribing practitioner, no later than 24 hours following the order. Responsibility for making the decision as to the emergency nature of the situation rests with the medical practitioner. Verbal orders can also be taken by a pharmacist. The pharmacist must record the order in the patient's medical record including the prescribing practitioner's name and affix his/her own signature. The practitioner must sign the order within 24 hours of the time it was given and provide the necessary prescription. The recorded order to either the registered nurse or pharmacist or respiratory therapist shall have the inscription, "Authorization for Emergency Dispensing."

(2) In cases of emergency **in a calamity area** where life or health is endangered, an order for dangerous drugs made not in the prescribed form and duly signed by the purchaser should be recognized by the licensed seller and forthwith supply the dangerous drugs so ordered. The purchase order should be signed by the City/Municipal Health Officer or attending medical practitioner or senior medical officer or police medical officer or military doctor or any available medical practitioner supervising the medical-dental-veterinary team or unit rendering medical-dental-veterinary service in the area, as the case may be, where the emergency situation arose. In any case, the head of the medical-dental-veterinary team of the lead agency or his designated representative, or head of the first responder medical team shall make

the purchase order. **On the face of the purchase order the following inscription, "Authorization for Emergency Dispensing." The drug ordered and dispensed must be limited to the amount needed to treat the patients during the emergency period. The person making the purchase shall be responsible for the proper safekeeping and accounting of the dangerous drugs.** The seller shall notify immediately the PDEA where the emergency occurred. The purchaser shall submit to the PDEA, a written statement of the circumstances leading to the purchase and how the medicine was secured, dispensed or administered and to whom, within seven (7) days after the particular emergency situation ended. **The pharmacy that dispensed the drug shall report to PDEA within seven (7) days after dispensing the drug. The notification to PDEA may be delivered in person or by mail. But if delivered by mail, it must be postmarked within the seven day period.**

((3)(a) In times of calamities or emergency situation where the President declares a national or local emergency situation, all medical practitioners and pharmacies of government and private hospitals, and those participating in field medical missions, whether foreign or domestic, in areas covered in the declaration are automatically granted appropriate temporary licenses and permits to deal, prescribe, handle, dispense, administer and store dangerous drugs during the duration of the emergency period. A medical practitioner may prescribe dangerous drugs in ordinary prescription, the S2 identification of which shall be stamped or printed "Emergency – (Name of Calamity)".

(b) In conformity with DOH Administrative Order Number 2007-0017 dated May 28, 2007, such hospital pharmacies may receive foreign donations of dangerous drugs with prior approval of FDA and DOH and PDEA. Hospital pharmacies and missions shall comply with recording requirements and submission of reports.

(c) Within ten days after the termination of the declaration of calamity, the medical practitioner, hospitals and medical missions with temporary emergency license still having stocks of dangerous drugs shall transfer the stocks of dangerous drugs to S3 licensed government hospital, with prior notification to PDEA. Transfer documents shall bear the notation, "Transfer of Dangerous Drugs After Emergency (Name of Calamity) Situation".

(d) Where the hospital pharmacy and medical practitioner with temporary license decide to obtain a regular S-license from PDEA, they shall secure the dangerous drugs but not dispense or administer it as the case may be, until the license is actually obtained and the dangerous drugs has registration with FDA.

Section 34. Emergency Situation Related to Filing of Emergency Order and Prescribing Dangerous Drugs

(1) The following are specified as falling within the category of emergency situation:

(a) as a result of man-made, natural and other disasters such as war in any form, terrorist attack, rebellion, insurrection, typhoons, **typhoon surge, tsunami**, earthquakes, volcanic eruptions, **massive** fire, deluge, grave accidents/**mishap**, epidemic, **and the likes** in which the health conditions of a group of individuals are seriously threatened unless immediate and appropriate action is taken, and which demand an extraordinary response and exceptional measures as to preclude prompt access to the official prescription form or order form for dangerous drugs;

(b) where, in the opinion of the prescribing practitioner, the immediate availability and administration of the dangerous drugs would save the life and/or alleviate the severe pain of the patient or euthanasia for the animal is required by the situation.

Section 35. Carrying of Dangerous Drugs and/or Drug Preparation containing Controlled Chemical by International Travelers.

(1) Any person undergoing treatment of a medical condition, who is entering, leaving or passing through the Philippines, may possess such quantities of a dangerous drug, or drug preparation containing controlled chemical, in any dosage form, wherever prescribed by a valid PDEA S2-licensed physician, as are reasonable for the purposes of such treatment.

(2) International traveler with pre-existing medical conditions shall carry the following items:

(a) Letter from attending physician, describing medical condition of the traveler (for incoming and outgoing passenger);

(b) Physician's prescription medication including the trade and generic names of the prescribed dangerous drugs and/or preparations or drug preparation containing controlled chemical (for incoming and outgoing passenger with dangerous drugs not exceeding thirty (30) days supply);

(c) Certificates of Authorizations issued by National Competent Authority of his home country and PDEA (for incoming passenger with dangerous drugs and/or drug preparation containing controlled chemical exceeding thirty (30) days supply);

(d) Certificates of PDEA Authorization and National Competent Authority of country of destination. (for outgoing passenger with dangerous drugs and/or and/ or drug preparation containing controlled chemical exceeding thirty (30) days supply);

(e) Prescription dangerous drugs and/or drug preparation containing controlled chemical in original/personalized container and properly labeled.

(3) Outgoing passenger must check with the Embassy of the country of destination for regulatory requirements for dangerous drugs or drugs under international control to be carried for personal use.

(4) Request for PDEA Authorization to carry dangerous drugs and/or drug preparation containing controlled chemical exceeding thirty (30) days supply shall be made in writing including letter from attending physician describing medical condition of the traveler, medication including the trade and generic names and Certificates of Authorizations issued by National Competent Authority of either his home country or destination country, to PDEA thirty (30) working days prior to arriving the Philippines. PDEA's reply will be made within fifteen (15) working days upon receipt of request."

Section 36. Exempt Officials or Persons and Institutions

(1) Government run-hospitals/clinics/dispensaries or similar institutions, universities and laboratories as well as responsible officials and employees in the active service of the national government agency and local government units, and government-owned or controlled corporations, and persons that have expressed exemption under special laws or charter, who in the exercise of their official functions or duties are engage in activities dealing with controlled substance shall register with the PDEA for the appropriate license. However, they shall be exempted from paying the corresponding fee for the license.

(2) A full-time government employed practitioner granted a PDEA S-2 license under Section 36(1) for dangerous drugs and/or drug preparation containing controlled chemical shall be exempted from payment of license. Authority to prescribe dangerous drug and/or drug preparation containing controlled chemical given to full time government medical practitioners shall be the same as what is provided for private medical practitioners.

(3) An S-2 licensed holder, who ceased employment with the government agency or government-owned or controlled corporation or institution shall inform PDEA-CS of such separation and return his S-2 license within five (5) working days from date of separation. He/She may apply for renewal or revalidation of his/her license as a private practitioner and pay the corresponding fee.

Section 37. Dangerous Drug and/or Drug Preparation containing Controlled Chemical Registers

(1) The following persons shall keep or maintain an appropriate dangerous drug register in accordance with the PDEA-prescribed format:

(a) any registered person granted a license or a permit under Article III of this Regulation in relation to any dangerous drug and/or drug preparation containing controlled chemical;

(b) any person authorized under Article III of this Regulation to issue a prescription or requisition for a dangerous drug and/or drug preparation containing controlled chemical , or to supply such a drug;

(c) any pharmacist, including a pharmacist responsible for the supervision of all other pharmacists employed in a hospital or other institution for medical treatment or care.

(2) (a) Every authorized pharmacist and PDEA licensed entity acquiring dangerous drugs and/or drug preparation containing controlled chemical shall maintain and keep an original record of sales, purchases, acquisitions, deliveries and disposal of dangerous drugs and/or preparations containing controlled chemical.

(b) For uniformity of records, the following are the prescribed register formats, which are made integral part of this Regulation:

Refer to Annex I.

(i) PDEA S Register 1-14 – Retail distribution / dispensing of dangerous drugs and/or drug preparation containing controlled chemical (drugstore setting)

(ii) PDEA S Register 2-14 – Retail distribution / dispensing of dangerous drugs and/or drug preparation containing controlled chemical (hospital setting)

(iii) PDEA S Register 3-14 – Wholesale Distribution of dangerous drugs and/or drug preparation containing controlled chemical

(iv) PDEA S Register 4-14 – Import and Distribution of dangerous drugs (raw materials)

(v) PDEA S Register 5-14 – Import and Distribution of dangerous drugs and/or drug preparation containing controlled chemical (finished products)

(vi) PDEA S Register 6A-14 – Manufacture of dangerous drug preparation and/or drug preparation containing controlled chemical

(vii) PDEA S Register 6B-14 – Distribution of locally manufactured dangerous drug preparations and/or drug preparation containing controlled chemical

(viii) PDEA S Register 7-14 – Research / Laboratory use of dangerous drugs and/or drug preparation containing controlled chemical

(ix) PDEA S Register 8-14 – Training school conducting programme for K-9 dangerous drug detector dog

(x) PDEA S Register 9-14 – Retention of manufactured dangerous drug preparations and/or drug preparation containing controlled chemical

(xi) PDEA S Register 10A-14 – S2 licensed physician/dentist acquiring dangerous drug and/or drug preparation containing controlled chemical stocks in accordance with Section 31(10)(a)

(xii) PDEA S Register 10B-14 – S2 licensed veterinarian acquiring dangerous drug and/or drug preparation containing controlled chemical stocks in accordance with Section 31(10)(a)

(3) (a) The register or computer print-out and semi-annual report (summary report) covering the period January to June or July to December certified to be true and correct and duly signed by the authorized pharmacist/practitioner/person and noted by the head of entity shall be submitted to PDEA, within fifteen days (15) days following the last day of June and December of each year.

(b) Licensed retailers and users for laboratory use/or programmes for medical, scientific research or instructional/training purposes shall submit semi-annual report as prescribed herein. Refer to Annex J

(c) In accordance with Section 4d of Board Regulation No. 7 s 2006 SUBJECT: Institutionalizing the Dangerous drugs Board Integrated Drug Abuse Data Information Network (DDB IDADIN), licensed importers, exporters, manufacturers and distributors of dangerous drugs/preparations shall submit semi-annual report as prescribed (DDB IDADIN Form 4-06).

(4) A person who makes entry in a drug register shall sign and date the entry.

(5) A person may, in the presence of a witness, correct, by notation, a mistake in an entry in the drug register, provided the person making the correction signs and dates the notation, and the witness

countersigns the notation.

(6) Any person required by this Section to keep a dangerous drug register shall, subject to any written direction to the person by PDEA, retain possession of the register, requisitions and commercial documents relating to entries therein for two (2) years after the date of the last entry in the register. Prescription that has been duly filled shall be retained by the pharmacist for a period of one (1) year from the date of sale of such drug. The used prescription booklet of the prescribing physician shall be retained for one (year) from date of full consumption. Such records shall be subject to review by the PDEA.

(7) Any person required under Subsection (1) to keep and maintain a register in relation to any dangerous drug shall record the transaction within **one hundred twenty (120)** hours of any import, export, manufacture, supply, acquisition or disposal.

(8) Any time supplies are wasted, including spillage, it must be documented in the register. The entry to be verified by a witness who shall countersign his/her name in the remarks column of the register.

Section 38. Controlled Chemical Register

(1) Any person granted registration, license or permit under Article III of this Regulation, in relation to any controlled chemical, unless otherwise exempted shall keep, or cause to be kept, at a place where any such chemical or item is kept by that person, or entity, a register in accordance with the prescribed format.

(2) Any person required under Subsection (1) to keep and maintain a register in relation to any controlled chemical shall within **one hundred twenty (120)** hours of any import, export, manufacture, supply, acquisition or disposal by that person of any such chemical or item, enter or cause the transaction in such register:

(3) For uniformity of records, the following are the prescribed register formats, which are made integral part of this Regulation:

- a) PDEA P Register 1-14 – Retail distribution of controlled chemicals
- b) PDEA P Register 2-14 – End-User / Importer-End-User / Research / Laboratory use of controlled chemicals
- c) PDEA P Register 3-14 – Wholesale Distribution of controlled chemicals
- d) PDEA P Register 4-14 – Import and Distribution of controlled chemicals
- e) PDEA P Register 5A-14 – Manufacture of controlled chemicals
- f) PDEA P Register 5B-14 – Manufacture of controlled chemical mixtures
- g) PDEA P Register 5C-14 – Distribution of locally manufactured or recycled controlled chemicals
- h) PDEA P Register 5D-14 – Recycle of controlled chemicals

(4) Any register required to be kept under Subsection (1), and all commercial documents relating to entries therein such as orders, invoices, dispatch notes, cargo manifests or customs or other shipping documents shall be kept for at least two (2) years after the end of the calendar year of the last entry in the register. Such registers may be subject anytime for review by the PDEA.

(5) (a) The register or computer print-out and semi-annual report (summary report) covering the period January to June or July to December certified to be true and correct and duly signed by the authorized signatory and noted by the head of entity shall be submitted to PDEA, within fifteen days (15) days following the last day of June and December of each year.

(b) In accordance with Section 4e of Board Regulation No. 7 s 2006 SUBJECT: Institutionalizing the Dangerous drugs Board Integrated Drug Abuse Data Information Network (DDB IDADIN), licensed importers, exporters, manufacturers and distributors of controlled precursors and essential chemicals / mixtures shall submit semi-annual report as prescribed. (DDB IDADIN Form 5-06).

(6) Any time supplies are wasted, including spillage or evaporation, it must be documented in the register. The entry to be verified by a witness who shall countersign his/her name in the remarks column of the register.

Section 39. False or Misleading Entries in Registers and Records

(1) Any person required to keep a register or other record under the Act and this Regulation shall not:

- (a) make, or cause or permit to be made, an entry in or on it that is false or misleading; or
- (b) cancel, obliterate or alter any entry, except to correct an error without obliterating the error.

Section 40. Duty to Notify PDEA of Losses of License or Import Permit, Export Permit or Local Order Permit or Special Prescription Form for Dangerous Drugs or Loss, Destruction or Discrepancies in Registers.

(1) Loss of license or import/export permits or local order permit or special prescription form for dangerous drugs.

(a) A license holder shall report the loss of license or import permit or export permit or local order permit or special prescription form for dangerous drugs to PDEA-CS or Regional Office in writing within forty-eight (48) hours from the time it was discovered lost, stating therein circumstances surrounding such loss.

(b) The concerned practitioner or operator shall submit an affidavit and police blotter relative to the loss.

(c) In case of loss of license, the licensee has the option to re-apply for a new license and pay for the corresponding fee.

(d) PDEA shall immediately thereafter declare such lost document invalid and notify its counterpart and cooperating agencies accordingly.

(2) Any registered person required to keep a register shall upon discovery, submit a written report within forty-eight (48) hours to PDEA:

(a) the loss or destruction of the register, or of the whole or any part of the contents of the register; or

(b) any discrepancy in the register, other than a mistaken entry.

(3). In any case, PDEA shall conduct investigation to determine whether the incident resulted from negligence or theft to commit drug diversion. Appropriate sanction or charges will be meted out to the licensed operator or practitioner.

Section 41. Safekeeping and Storage and Transporting of Controlled Substance

(1) Any person authorized:

- (a) to import, export, manufacture, supply, administer, or acquire a controlled substance;
- (b) to engage in professional supply of dangerous drugs or drug preparations, in parenteral form, containing controlled chemical;
- (c) to conduct research, laboratory analysis or technical or teaching/training program,

shall be responsible for all aspects of the safe and secure storage and handling of controlled substances, including knowledge of fire/building code that will be required for compliant storage practices.

(2) A person referred to in Sub-section (1) shall take such measures to ensure that no unauthorized person has access:

(a) to the combination, key or other means of access to any secured storage facilities or depot for controlled substance; or

(b) to the controlled substance contained therein.

(3) The licensed operator shall ensure that the safekeeping and handling of the chemicals is in accordance with the requirements defined in the Material Safety Data Sheet of the chemical concerned and in accordance with PDEA prescribed guidelines on safekeeping, storage, use and transport. Refer to Annex G

(4)(a) When transporting controlled substances:

(i) Transfer of controlled chemicals, except raw material of Table I precursor chemical used in the manufacture of pharmaceutical drug preparation as indicated in Section 6 (4)(a)(i), from one licensed operator to another or from one address to another, shall be accompanied by the following documents indicating:

- (1) the name and quantity of the controlled chemical;
- (2) the name of the licensed dealer/supplier of the controlled chemical to be transported;
- (3) the name of the PDEA accredited transporter, and the driver and helper at the time of transport;
- (4) the name of the purchaser to whom the controlled chemical is to be transported or delivered;
- (5) copy of the PDEA license of the supplier;
- (5) delivery or sales receipt and/or invoice receipt including the corresponding lot or batch or control number;
- (6) MSDS or Safety Data Sheet or latest version of the globally harmonized system-based (GHS-based) version of the chemicals, which shall be kept by the person-in-charge of making the delivery; and
- (7) the date and time the controlled chemical was delivered .

(ii) transport of hazardous controlled chemicals shall also be in accordance to the JOINT DTI-DENR-DA-DOF-DOH-DILG-DOLE-DOTC ADMINISTRATIVE ORDER NO. 01 Series of 2009 Subject: The Adoption and Implementation of the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals and regulations pertinent thereto that are issued by implementing agencies and this Regulation.

(iii) Key locks or safe combinations should be changed whenever personnel changes occur, or on a prearranged schedule determined by the department chair or responsible officer of the entity. Gauges or calibration shall be in working condition at all times.

(5). Disposal of Controlled Substance.

(1) Dangerous Drugs and Drug Preparations containing Controlled Chemicals

(i) All licensed operators except in a hospital/clinic setting that has an inventory of controlled drug preparations for disposal shall secure an approved local order permit from the PDEA Compliance Service and notify the PDEA Laboratory Service or PDEA Regional Office in writing and surrender the item. Upon acknowledgement of the receipt thereof, a copy shall be submitted to Compliance Service for reference and notation in the Dangerous Drugs Register.

(ii) In cases where the disposal of controlled drug preparations will be through a destruction facility, the facility shall be DENR registered and compliant with the prescribed manner of disposal. It shall be notified to PDEA Laboratory Service in which case a PDEA Laboratory personnel shall witness the actual destruction. A copy of the destruction report shall be submitted to Compliance Service for notation in the register. The licensed operator shall bear the cost of disposal.

(iii) Hospitals. Individual doses of dangerous drugs which are prepared but not administered, syringe contents of partly-used ampoules, residual unused content of dangerous drugs in ampoules and vials, unused volumes of infusions, unused, unopened or out of date products shall be returned to the issuing pharmacy for recording, and proper disposition.

(1) Procedure in case of waste, destruction, contamination etc . in hospital setting

(a) Aliquot part of controlled drugs used for dose: Where the nurse withdraw the required amount of tablets or ampoules from nursing stock, he/she shall record the number of tablets or ampoules used and the dose given in the proper columns on controlled drugs administration record sheet. He/she shall, in arriving at the pre-determined aliquot part, return that portion of the solution that is not used to the pharmacy for proper disposition.

(b) Prepared Dose refused by Patient or Cancelled by Doctor: When a dose has been prepared for a patient but not used, due to refusal by the patient or cancellation by the doctor, the attending nurse shall return the drug to the pharmacy for proper disposition and record why the drug was not administered . The nurse in charge of the ward shall countersign the statement of the attending nurse.

(c) Accidental Destruction and Contamination of Drugs: When a solution, ampoule, tablet etc., is accidentally destroyed or contaminated in the ward, the person responsible shall indicate the loss on the daily controlled drug wastage record sheet and the nurse-in-charge of the ward shall return the contaminated drug to the pharmacy for proper disposition.

(d) When it is necessary to "waste" part of a dangerous drug unit on the ward or clinic, two entries must be made.

(i) The first entry must be the dose given (one-half ampoule, 25 milligrams (mg), etc.).

(ii) The second entry will be the amount wasted (one-half ampoule wasted, 25 mg wasted,

The nurse in charge of the ward or clinic may waste a partial dose of the dangerous drug. An authorized nursing employee must witness this wasting. The amount "wasted" must be secured in a waste bin and **properly recorded/documentated**.

(2) Disposition of expired dangerous drugs and/or drug preparation containing controlled chemical.

Every month the hospital pharmacy shall notify the PDEA of all expired dangerous drugs and/or drug preparation containing controlled chemical in its possession and surrender them to the PDEA Laboratory Service or PDEA Regional Office who will witness the destruction by authorized methods. If the destruction is done in a DENR- registered destruction facility, the cost of destruction shall be borne by the licensed supplier or operator.

(3) Documentation of the transfer of items for return or surrender or destruction shall be through a permit system and shall indicate the drug name, dosage form, strength, quantity, and date of transfer, names and signatures of persons making the turn-over and the person receiving, including two witnesses.

(b) Controlled Chemicals

(i) All licensed operator that has an inventory of expired, or damaged, or contaminated controlled chemicals for disposal shall notify the PDEA Laboratory Service or PDEA Regional Office in writing for intention to surrender the chemicals. Where the quantity is substantial, and after due inventory and recording by PDEA, the concerned operator shall make arrangements for the transfer of the chemicals directly to a DENR registered chemical disposal company. The license operator shall bear the cost of disposal by authorized means. Upon disposal thereof, a copy shall be submitted to PDEA Compliance Service for notation in the Controlled Chemical Register.

(ii) A licensed operator disposing waste material containing controlled chemical(s) shall check whether the DENR registered waste disposal company recycles the waste chemical for its

controlled chemical content, and if it does, should be asked for its PDEA license as a recycler.

Section 42. Duties Where There is Loss or Theft of a Controlled Substance

(1) Any person authorized:

- (a) to import, export, manufacture, administer, supply or acquire a controlled substance; or
- (b) to engage in professional supply of dangerous drugs or drug preparations, in parenteral form, containing controlled chemical,
- (c) to conduct research, laboratory analysis or technical or teaching/training program,

shall immediately report to PDEA-CS or Regional Office, as the case may be, in writing, within forty -eight (48) hours after becoming aware of the occurrence of theft or unusual waste or unexplained disappearance of any specified quantity of the controlled substance in the person's custody or control and record relevant particulars of the loss or theft in the appropriate register. The license holder shall inform of the circumstances of the loss including trade name of controlled substance or preparation and quantity, and if lost in transit, name of carrier, name and PDEA license of consignee, whether the shipment was received by the consignee.

(2) Where loss of the whole or part of a shipment occurred while en-route to destination, the deliverer/transporter shall render a report to PDEA within forty -eight (48) hours. Where discrepancy is discovered while the shipment is in the process of acceptance, the receiver shall render a report and also inform the seller. In any case, where the shipment is not yet fully accepted by the recipient, the security of and accountability for the shipment while en-route to its destination shall remain the responsibility of the seller.

(3) PDEA shall conduct investigation for probable commission of drug or chemical diversion, and also determine whether the security provided for the storage of controlled substances registrant/licensee is inadequate.

(4) PDEA licensed manufacturer, importer/exporter, distributor of controlled chemical solvents shall install efficient industry evaporation control system in storage, industrial production, and transport operation to control and reduce losses due to evaporation and handling. Annual evaporation loss and handling loss shall not exceed 0.5 per cent of total annual (calendar year) inventory.

Section 43. Controlled Substance Containers and Labeling and Relabeling Requirements

(1) Dangerous Drug and Drug Preparation containing Controlled Chemical shall conform with the Food and Drug Administration requirement on packaging, labeling and relabeling.

(2) Suppliers of controlled chemicals shall ensure that:

(a) Controlled chemicals, including repackaged chemicals and commercial products that are mixtures of chemicals shall be kept in appropriate containers with labels as indicated in the Material Safety Data Sheet or Globally Harmonized System Safety Data Sheet (GHS-SDS) of the particular controlled chemical, until such time that the GHS-SDS will have become the effective standard SDS.

The containers should have importer's/manufacturer's/distributor's labels, indicating at the minimum, the following information

- (i) the product name as stated on the MSDS or Safety Data Sheet
- (ii) Identity and concentration of chemical components
- (iii) Danger markings; safety precautions
- (iv) Risks associated with the use of the chemical and first aid steps
- (v) Details of manufacturer/importer and address and emergency contact number
- (vi) MSDS or Safety Data Sheet number, reference that MSDS or SDS is available.

(vii) Importer's/Manufacturer's/distributor's Lot or Batch Number

(b) the container (excluding containers intended for retail sale for personal use) in which the controlled chemical is stored shall be clearly marked with paint or permanent ink on the outside thereof, including the English name of the substance, the batch number with unit (drum/carbouy/pail) number and name of seller. Said markings shall not be removed/ wiped out unless content is consumed and subject container shall be reused.

(c) the container shall not contain any substance other than the substance so marked thereon;

(3) The MSDS or GHS-SDS shall contain PDEA prescribed minimum information where applicable and available as prescribed in Annex M.

(4) Where an empty labeled container that previously contained a controlled chemical, will be sold to another, the seller shall totally erase the label of the container, except when the container is returned back to the original importer/distributor or manufacturer/distributor.

ARTICLE IV ADMINISTRATION, COMPLIANCE AND ENFORCEMENT

Section 44. Appointment/Designation of Regulatory Compliance Officers

(1) The Director General , PDEA shall appoint, designate and/or assign qualified and adequately trained PDEA personnel, as Regulatory Compliance Officers for the purposes of the Act and this Regulation.

(2) PDEA shall cause to be issued to the Regulatory Compliance Officer, an identification card which states the name and appointment of Regulatory Compliance Officer and on which appears a recent photograph of the officer.

Section 45. Inspection of Authorized Premises and Operations

A PDEA license holder shall, when required to do by a visiting Regulatory Compliance Officer open the registry for controlled substance, including drug preparations, containing controlled chemical for inspection. Such person shall, when required to do in writing, provide the PDEA officer with a statement in writing, signed and dated by the person, account for each dangerous drug, or controlled chemical in possession of the authorized person at any time since the grant of the registration/license, or permit.

Section 46. Duties of PDEA Regulatory Compliance Officers

(1) A person duly designated or assigned as PDEA Regulatory Compliance Officer by the Director General, PDEA and armed with a letter/mission order may, at any time during ordinary business or professional hours of the practitioner or operator, with such assistance and by such force as is necessary and reasonable, enter any premises or place at which any activity is carried out by any person in accordance with the license provided by PDEA .

(2) A Regulatory Compliance Officer who enters any premises or place pursuant to subsection (1) shall:

(a) require the occupant of the premises to supply his or her name and address;

(b) inspect the premises or place in order to ascertain whether or not the Act, or a term or condition of any license or permit granted pursuant to this Regulation has been or is being complied with;

(c) examine any label, advertising material, register/book, records, electronic data or other pertinent document therein relating to any controlled substance;

(d) take an extract of the record or pertinent document or take a copy thereof, and require from the head of the entity and authorized signatory a notarized explanation of an entry in any such register, record or document;

(e) take photograph/s or video footage/s of the controlled substance and container, and premises where it is stored;

(f) open and examine any receptacle or package found in that place in which a controlled substance may be found;

(g) examine anything found in that place that is used or may be capable of being used for the manufacture, packaging or storage of a controlled substance;

(h) examine any substance found in that place and take, for the purpose of analysis, such sample/s thereof as are reasonably required. The Officer shall issue a receipt for the sample/s taken;

(i) seal and seize container/s containing a controlled substance found not properly documented or authorized;

(j) examine that the stocks of controlled substance are stored in appropriate and secured facility;

(k) examine that controlled substances have not been loaned or shared with other wards or laboratories or individuals not otherwise authorized to receive them nor transferred to other accounts;

(l) examine that all handlers have completed background check and a statement to that effect is in the personnel file;

(m) examine that locks and/or safe combinations have been rekeyed/changed whenever personnel turnover occurs;

(n) examine that all controlled substances are stored according to their labeled instructions and MSDS;

(o) examine that disposal of any expired materials or empty containers have been done via proper channel;

(p) examine claims and/or paid insurance for loss of controlled chemical while en- route to buyers and compare them with reports of loss to PDEA;

(q) access records of personnel involved in the handling of controlled substances; and

p) where the offense committed is mitigable, provide relevant advice or information for immediate corrective action to the responsible persons about pertinent Rules and Regulations.

(3) The PDEA Regulatory Compliance Officer shall ask for a signed certificate from the occupant of the premises that the conduct of inspection was reasonable and properly done.

(4) Where in the ordinary course of duty, a Regulatory Compliance Officer becomes aware of any possible violation of the provisions of the Act and this Regulation, he or she shall immediately report that fact to the Director General, PDEA or Director of Compliance Service or Regional Director of PDEA . and proceed with the reasonable or necessary investigation or proceeding relating to that possible offense.

(5) Conduct intelligence-led investigation of probable diversion of licit controlled substances for illegal purpose.

(6) Conduct monitoring of movements of significant quantities of controlled substances in the supply chain.

(7) In the conduct of administrative inspections, where the situation necessitates that PDEA Regulatory Compliance Officers may make seizure of controlled substances without a warrant, the PDEA Regulatory Compliance Officers shall act accordingly:

(a) With the consent of the owner or operator in charge of the controlled premises;

(b) In situations presenting imminent danger to health or safety;

(c) In situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(d) In any other exceptional or emergency circumstance where time or opportunity to apply for

a warrant is lacking; and

(e) In all other situations where a warrant is not a requisite.

(8) Except **during the conduct of a criminal or diversion investigation or authorized by the circuit criminal court or** when the owner, operator, or person in charge of the controlled premises so consents in writing, no inspection authorized by Section 48 shall extend to:

(a) Financial data;

(b) Pricing data; or

(c) Research data.

Section 47. Presentation of Authority to Conduct Inspection/Compliance Investigation

(1) A PDEA Regulatory Compliance Officer shall present his or her duly issued PDEA identification card and letter/mission order to the person in charge of any place entered pursuant to this Regulation for the purposes of inspection. **In no case shall it be photocopied by the licensed operator who is subject of the inspection.**

(2) Any person who claims to have regulatory powers and who enters a licensed establishment in accordance with this Regulation, is not authorized to remain in the premises if the person does not present the duly PDEA issued identification card and letter/mission order, and the licensed holder or any person in or on the premises is not obliged to comply with the requirement of that person claiming such authority.

Section 48. Coordinating System

(1) The PDEA and other concerned agencies, in cooperation with concerned stakeholders shall establish an effective operational monitoring and inter-agency coordination and cooperation mechanism or system.

(2) PDEA and all licensed importers and exporters of controlled substances shall actively and effectively participate in the National Single Window program and other similar programs of the government or inter-governmental organizations or the United Nations to improve efficacy of service delivery, and detect and prevent diversion of controlled substances.

Section 49. Obstruction of Regulatory Compliance Officer

No person shall, without reasonable excuse, by act or omission:

(a) obstruct or hinder or refuse entry of a PDEA Regulatory Compliance Officer in the performance of his duties under this Regulation and other pertinent Board issuances within a period of two (2) hours; and

(b) refuse or fail to comply with a valid request of a PDEA Regulatory Compliance Officer who has entered any premises in accordance with RA 9165 and this Regulation and other related Board Issuances within fifteen (15) days after said request was made.

Section 50. Liability for Violation of Regulation.

(1) Any person found in violation of this Regulation shall be subject to the following penalties:

i. First Violation – a fine of P 20,000.00 and a warning that a repetition of the same offense will be dealt with more accordingly.

For shipment of **controlled substance** by licensed operator without an approved import permit from the PDEA, a fine amounting to 15% of the total value of the shipment or P 50,000.00, whichever is higher.

For violations committed due to unintentional lapses, simple negligence or without any tint of malice- a written Reprimand with warning that repetition of the same will be dealt with accordingly.

- ii. Second Violation of the same provision of this Regulation - a fine of P35,000.00 and a warning that a repetition of the same offense will be dealt with more severely.

For shipment of **controlled substance** by licensed operator without an approved import permit from the PDEA, a fine amounting to 30% of the total value of the shipment or P 50,000.00, whichever is higher, and a recommendation from the PDEA that the shipment be subjected to forfeiture proceedings.

- iii. Third Violation of the same provision of this Regulation – responsible officials and persons shall be criminally liable for violation of Section 32, Article II of the Act in addition to the suspension or revocation of license, as the case may be.

For shipments of controlled substance by licensed operators without an approved import permit from the PDEA, a fine amounting to 50% of the total value of the shipment, or P50,000.00, whichever is higher, with a recommendation from the PDEA that the shipment be subject of forfeiture proceedings and responsible officials and persons shall be criminally liable for violation of Section 32, Article II of the Act.

2. PDEA's decision may be appealable to the Dangerous Drugs Board Committee on Appeals as provided for in Board Regulation No. 5, Series of 2008 within fifteen (15) days from receipt or knowledge of the PDEA's denial of reconsideration.

Section 51. Transitory Provision

All previous and existing S2 license holders with back accounts and penalties due to non-notification to the PDEA on the retirement or discontinuance of use of the said license shall not be charged from payment of the same, provided, that the practitioner shall renew his/her S2 license within a period of six (6) months following the approval and adoption of this Regulation.

Section 52. Repealing Clause

Board Regulations No. 3 – Series of 2003, No. 5 – Series of 2006, No. 6 – Series of 2007, No. 2 – Series of 2009, and all other Resolutions, Orders and Rules and Regulations which are inconsistent with this Regulation are hereby repealed. Board Regulations No. 3 – Series of 2005, No. 5 – Series of 2008 and No.1-Series of 2010 are hereby amended or modified accordingly.

ARTICLE V EFFECTIVITY

Section 52. Effectivity. This Regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation and fifteen (15) days after registration with the Office of National Administrative Regulations, UP Law Center, Quezon City.

Done in Quezon City this ___ day of _____, 2014