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 2019

SUBJECT: Revised Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensation, Trading, Administration, 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 Republic Act no. 9165, as amended by Republic Act no. 10640, article xi, Section 93, the Dangerous Drugs Board hereby promulgate the following guidelines:

ARTICLE I
Definition of Terms

Section 1. Definitions. – In these 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** - any substance whose chemical structure is substantially similar to any dangerous drug whose psychoactive effects are simulated by the substance.

(d) **Article** - a manufactured item other than a fluid or particle (i) which is formed into 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.

(e) **Brand Name** - is the proprietary name given by the manufacture to distinguish its product from those of competitors.

(f) **Board** - refers to the Dangerous Drugs Board under Section 77, Article IX of RA 9165. (All DDB found in the provisions will be changed to "Board").

(g) **Customs broker** - means any person who is a 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 the Bureau of Customs.

(h) **Controlled Precursors and Essential Chemicals** - includes those listed in Tables I and II of the 1988 UN Convention Against Illicit Traffic in Narcotics Drugs and Psychotropic Substances as enumerated in the attached annex and those classified and may hereinafter be classified by

the Board as such. The term CPECS, likewise, includes any preparations or mixtures, containing its salts or isomers or analogs, and those similarly designed or newly introduced chemicals and their derivatives, without having any therapeutic value or if the quantity is far beyond therapeutic requirements.

(i) **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. The term dangerous drugs, likewise, includes any preparation or mixture, containing its salts or isomers, or analogs, and those similarly designed or newly introduced drugs and their derivatives, without having any therapeutic value or if the quantity is far beyond therapeutic requirements.

(j) **Dispense(Pharmacy Law)** - means any act of giving away, selling or distributing medicine or any dangerous drug or with or without the use of prescription.

(k) **Distributor** - any person or entity that procures raw materials, active ingredients and /or finished products for distribution to any person or entity.

(l) **Diversion** - the sale, distribution, supply or transport of legitimately imported, in-transit, manufactured or procured controlled precursors and essential chemicals and dangerous drugs or in any dosage form, in diluted mixtures or in concentrated form, to any person or entity for illicit purposes, and shall include packaging, repackaging, labeling, relabeling or concealment of such transaction through fraud, destruction of documents, fraudulent use of permits, misdeclaration, use of front companies or mail fraud.

(m) **Emergency Cases** - refer to life-threatening illness or injury where a patient needs immediate medical attention and treatment.

(n) **Entity** - means any person, natural or juridical, including among others, an individual person, 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.

(o) **Exportation** - refers to the act, process or transaction involving the bringing of goods out of Philippine territory.

(p) **Finished product** - refers to a combination of raw materials/chemicals that have undergone a process and attained its end result.

(q) **Floor Stock** - refers to stocks at the floors outside the pharmacy premises in the central pharmacy or in its satellites as approved by the Therapeutics Committee or by the appropriate hospital official or unit, such as, but not limited to, the following: a) Emergency carts; b) STAT medications; c) medical specialty units for immediate access for the medication to address emergency cases and other urgent cases such as severe pain or seizures.

The term does not cover standing or routine medications. The stocks shall be managed by a trained nurse or a pharmacy assistant under the supervision of a licensed pharmacist.

(r) **Generic Name(Generics Act)** - refers to the scientifically and internationally recognized name of the active ingredients, as approved by

the FDA pursuant to R. A. No. 6675, otherwise known as the "Generics Act of 1988".

(s) **Hospice care** - refers to the palliation of a chronically, terminally, or seriously ill patient's pain or symptoms, otherwise known as end-of-life care that consists of medical, psychological and spiritual support.

(t) **Importation** - refers to the act of bringing into the Philippines territory any dangerous drug and/or Controlled Precursors and Essential Chemicals.

(u) **Medical Institution** - refers to 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.

(v) **International Drug Control Conventions** - refers to 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.

(w) **License** - refers to written authorizations issued by the Director General of PDEA or his authorized representative, classified as follows:

(i) S-License refers to the authority to perform specific acts relative to the handling, custody and disposition of dangerous drug;

(ii) P-License refers to the authority to perform specific acts relative to the handling, custody, and disposition of controlled precursors and essential chemicals

(x) **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 substance, 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.

(y) **Material Safety Data Sheet or MSDS or Safety Data Sheet or SDS** - is (i) a widely used system for cataloguing information on chemicals, chemical compounds and/or mixtures which contain 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.

(z) **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.

(aa) **Medical Specialty Units** - refer to areas, which are within the premises of a Medical Institution, where procedures are performed that require the use of dangerous drugs in bulk such as, but not limited to, the following; a) Operating Room b) Emergency Room c) Delivery Room; d) endoscopy unit; e) dialysis or renal unit; f) Oncology infusion unit; and g) Other facilities analogous to the functions of the foregoing.

(bb) **Opioid** - means any synthetic narcotic drugs that produces the same effects with those derived from the opium poppy (opiates), such as pain relief, sedation, constipation and respiratory depression.

(cc) **Operator** - an entity who engages in the importation, distribution, manufacture, prescription, dispensation, trading, administration, sale of, cultivation, and other lawful acts in connection with dangerous drugs, controlled precursors and essential chemicals.

(dd) **Palliative Care** - is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

(ee) **Pharmaceutical Equivalents** - dangerous drugs containing the same active ingredient(s), same dosage form and route of administration, and have identical strength or concentration.

(ff) **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, dentist, veterinarian, or any other health care provider.

(gg) **Permit** – is a transactional authorization granted in writing by the PDEA Director General or his authorized representative to a S or P licensee for the importation, distribution, manufacture, dispensation, trading, sale of, cultivation and other lawful acts in connection with dangerous drugs, controlled precursors and essential chemicals.

(hh) **Pharmacist** - refers to a health professional who has been registered and issued a valid Certificate of Registration (COR) and Professional Identification Card (PIC) by the PRC Board of Pharmacy (BOP).

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

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

(kk) **PDEA-LPS** - refers to PDEA Legal and Prosecution Service.

(ll) **PDEA-IU** - refers to PDEA Interdiction Unit.

(mm) **Prescription** - means a written direction by a medical practitioner that a stated dose, frequency, route of administration, and quantity of a dangerous drug in any form be dispensed to the patient named therein.

(nn) **Preparation or Mixture** - refers to a product, in whatever physical state or form, where the following substances, including their salts and isomers are used, *viz:*

(i) A dangerous drug; or
(ii) A controlled precursor and essential chemical

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Provided, preparations of Norephedrine/Phenylpropanolamine at doses of 25 mg or below shall be exempt from the application of this Board Regulation

(oo) **RCMIS** - Regulatory Control Monitoring Information System, A web-based system to receive, gather, collect, collate all data and information on the importation, exportation, production, manufacture, distribution, dispensing, sale, stocks, seizures and the estimated need for any dangerous drugs and or controlled precursors and essential chemicals, preparations and mixtures.

(pp) **Sale** - refers to the transaction or act of giving away any dangerous drug and/or controlled precursor and essential chemical whether for money or any other consideration.

(qq) **Satellite pharmacy** - refers to a pharmacy situated within a medical institution which provides specialized services for patients in the area where it is located. A satellite pharmacy is dependent on the central pharmacy for administrative control, staffing and drug procurement.

(rr) **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.

(ss) **Therapeutic dose** - means the quantity which is required to elicit the desired therapeutic response of the patient in the treatment of disease or ailment.

(tt) **Transshipment** - Shipment transfer between carriers or from one vessel to another vessel in transit.

(uu) **Use** - means any act of injecting, intravenously or intramuscularly, or 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 a controlled chemical.

(vv) **Volatile substances** - includes 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, stryene, 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 behavior or in any manner changing, distorting or disturbing the auditory, visual or mental processes, as provided for in Presidential Decree No 1619.

ARTICLE II
CLASSIFICATION

Classification of DDs and CPECs

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

(1) dangerous drugs and their preparations and drugs containing controlled chemical classified by the Board and introduced in the Philippines for medical, dental, veterinary practice use and research purposes shall be registered with the Food and Drugs Administration and, likewise, be classified as follows under the Philippine Schedule :

Schedule 1 has no currently accepted medical use in treatment in the Philippines; has lack of accepted safety for use of the drug under medical supervision.

Schedule 2 may have currently accepted medical use in treatment in the Philippines; has high potential for abuse that, may lead to severe psychological or physical dependence.

Schedule 3 has a currently accepted medical use in treatment in the Philippines; has a potential for abuse less than the drug in schedules 1 and 2 that may lead to moderate or low physical dependence or high psychological dependence.

Schedule 4 has a currently accepted medical use in treatment in the Philippines; has a low potential for abuse less than the drug in schedule 3 that may lead to limited physical dependence or psychological dependence.

Schedule 5 has a currently accepted medical use in treatment in the Philippines; has potential for abuse that may lead to from low to high psychological or physical dependence. Dangerous Drugs in the Philippines only.

(2) 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.

The Board may, on good ground, upon a written application, and after evaluation, issue a Certification that a substance is not classified as a Dangerous Drugs or CPECS. Such Certification shall be valid for a period of one year, without prejudice to the revocation of the same by the Board sooner on good grounds**.**

Likewise, importers, exporters of non-controlled, non-scheduled preparations and chemical mixtures shall submit to the Board the updated Material Safety Data Sheet or Safety Data Sheet and/or Certification from Supplier confirming the absence of controlled chemicals in the mixtures.

A fee of P 300.00 shall be charged per Certification of ten (10) items. Exempted from payment of fees are national and foreign government agencies.

Section 3. ***Reclassification, Addition, or Removal of Any Substance from the List of Dangerous Drugs.*** - the Board, pursuant to Section 93 of Article XI of the Act, has the authority and power to reclassify, add to, or remove from the schedules any substance;

Provided, notifications communicated by the Secretary General of the United Nations to the Board of its decision to include or exclude a substance in the Schedule or Table of International Controlled Substances under the international drug control conventions. The Board is mandated to issue a Board Regulation to declare such substance as included or excluded in the lists of dangerous drugs or controlled precursors and essential chemicals.

For the purpose of public hearings, the Board shall convene a Committee which shall be headed by a Permanent Member of the Board and representatives from the Board Secretariat, PDEA, Food and Drug Administration, Office of Health Regulations of the Department of Health, NBI, PNP Crime Laboratory, UP-PGH National Poison Management and Control Center and Department of Justice, as regular members. The Committee may invite resource persons from the field of drug and chemical control for consultation meetings. The Committee shall gather and collate all data relative to the drug or chemical under consideration and submit a report of its findings and recommendations to the Board.

Provided, that the Board shall also take into accord the obligations and commitments to international treaties, conventions and agreements to which the Philippines is a signatory.

Provided, further, that in conformity with the task given by International Narcotics Control Board (INCB) as the government focal point, the Board shall establish and maintain an online communication platform dedicated to real time communication and exchange of information that will enable and support intelligence generation and dissemination of information on incidents involving suspicious shipments of, trafficking in, or manufacture or production of NPS; diversion of non-scheduled, non-controlled chemicals that are not listed in Tables I or II of the 1988 Convention, and substitute chemicals either in a pure form, chemical mixtures, finished products or preparations that are frequently used in the illicit manufacture of drugs.

Provided, furthermore, that the Board shall create a Technical Working Group (TWG) which shall consist of representative from the Board Secretariat, Philippine Drug Enforcement Agency (PDEA), Bureau of Customs (BOC), Food and Drug Administration (FDA), Department and Natural Resources-Environment Management Bureau (DENR-EMB), Department of Trade and Industry – Bureau of Import Services (DTI-BIS), Philippine Economic Zone Authority (PEZA) as regular members. The TWG shall be headed by a Permanent Member of the Board who shall preside over the meetings. It shall assist the Board in the formulation of guidelines and practical responses to handle, control, and monitor non-scheduled, non-controlled substances or chemicals, and New Psychoactive Substances (NPS) to reduce and prevent the risk of diversion and unauthorized entry of non-controlled chemicals and substitute substances. The TWG shall notify the Board of the data collected relative to the non-scheduled, non-controlled substances or chemicals, and New Psychoactive Substances (NPS) and chemicals and submit a report to the Board of its observations, findings and recommendations for its inclusion in the list of controlled substances under the Philippine Schedule.

To this end, the Compliance Service shall submit to the Board a copy of quarterly reports on the Importation, Distribution, Manufacture, Prescription, Dispensation, Trading, Administration, and Sale of, and other Lawful Acts in Connection with Any Dangerous Drugs, Controlled Precursors and Essential Chemicals and Other Similar or Analogous Substances, stocks, seizures and estimated need for dangerous drugs and controlled precursors and essential chemicals in compliance to the reportorial requirements imposed by the INCB, UNODC, WHO, and CND in consonance to the country's international commitments and implementation of the provisions of the international drug control conventions. The Board shall report to the INCB such data whenever necessary.

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Provided, finally, all Importation, Distribution, Manufacture, Prescription, Dispensation, Trading, Administration, and Sale of, and other Lawful Acts in Connection with Any Dangerous Drugs, Controlled Precursors and Essential Chemicals and Other Similar or Analogous Substances; and of non-controlled chemicals that are frequently used in the illicit manufacture of drugs shall register and report with the Regulatory Control and Monitoring Information System (RCMIS).

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Section 4. *Preparations and Mixtures.* –Preparations and mixtures shall be subject to full regulatory control measures, except when exempted from certain regulatory measures or when a Certificate of Exemption has been issued, upon prior written application by a licensee before the Board or the Secretariat, as the case may be, not later than ten (10) days prior to the intended date of transaction, as provided hereunder:

(1) The Dangerous Drugs Board ~~Secretariat,~~ through the Executive Director, may exempt a specific transaction or act covering a preparation or mixture from specific regulatory control measures, subject to the following:

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a) the preparation or mixture is not in parenteral form and is compounded in such a way that it will not pose any risk of abuse.
b) the preparation or mixture does not contain more than one dangerous drug;
c) the dangerous drug cannot be easily extracted from the preparation or mixture in a quantity likely to present any risk of abuse;
d) the exemption is necessary for a legitimate medical purpose;

If the preparation or mixture, is necessary for an academic, research, scientific, or training purpose, the approval shall only be made by the Board.

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(2) In-vitro diagnostic reagents, buffers, and analytical standards, and test kits for diagnostic tests to determine drugs in body fluids or nature of disease may be exempted by the DDB Secretariat from certain regulatory control measures.

(3) solid, semisolid and highly viscous chemical mixtures, finished products, and or preparations containing Table II chemicals may, likewise, be exempted by the DDB Secretariat.

(4) FDA-registered preparations intended for oral administration, containing ergometrine/ergonovine, ergotamine, norephedrine, and their salts may, likewise, be exempted by DDB Secretariat.

(5) Compounded galenical preparations containing potassium permanganate intended as disinfectant, antibacterial and antifungal agents intended for medical use may, likewise, be exempted by DDB Secretariat.

Provided, that the importer, exporter, manufacturer, distributor, seller, trader or broker shall promptly report to the Secretariat, through the RCMIS online system, and the PDEA, through its Interdiction Unit, the importation, exportation, manufacture, distribution, sale, trading or brokerage of any of the said articles including their preparation and mixtures. In no case shall the report be delayed for more than seventy-two (72) hours from the date of the transaction.

(6) The Board Secretariat shall monitor the compliance of an entity granted Certificate of Exemption/ Board Resolution for Exemption of the conditions stated therein. The Certificate of Exemption issued shall be valid for period of six (6) months.

In case of a violation of any of the conditions stated in the Certificate of Exemption, the transaction or act covered by the said certificate shall be deemed invalid and unauthorized. Hence, the entity shall accordingly be held responsible.

(7) The DDB Secretariat shall maintain an electronic registry of all transactions it exempted under this Section, specifying each regulatory control measure from which it is exempted through RCMIS information system. Likewise, the same shall provide an access to the PDEA relative to the information portal developed by the DDB Secretariat.

(8) A fee of Five Hundred Pesos (₱500.00), per ten (10) items, shall be charged. Exempted from the payment of fees are national government agencies and government owned or controlled corporations and foreign counterpart regulatory or enforcement agencies.

ARTICLE III
REGISTRATION, LICENSING, PERMIT, AND ACCREDITATION SYSTEM

Section 5. **Regulatory Control Measures of PDEA** ~~***Requirements for Registration, Licensing, Permit, and Accreditation of Entities engaged in the Importation, Exportation, Transportation, Transshipment, Cultivation, Distribution, Manufacture, Prescription, Dispensation, Trading, Administration, and Sale of, and other Lawful Acts in connection with the handling of Dangerous Drugs or Controlled Precursors and Essential Chemicals***~~**.** – The applicable regulatory control measures which the PDEA shall impose are the following:

~~(a) Licensing entities;~~

~~(b)~~(a) ~~Granting of~~Registration and/or grant of a license; ~~transaction-based permits to licensees;~~

~~(c)~~(b) (Section 5(b) OLD) In the case of importation, exportation, transportation, transshipment, cultivation, distribution, manufacture, prescription, dispensation, trading, administration, and sale of, and other lawful acts in connection with the handling of dangerous drugs or controlled precursors and essential chemicals, and other analogous activities, registration and/or licensing:

(i) import, transit, and export permits issued to the operator by the PDEA for each of such activities;

(ii) a permit for each intended activity or transaction;

(iii) an export permit for each intended export transaction shall only be issued upon prior receipt of an import certificate issued by the competent authorities of the country of intended destination;

Section 6. **(After Section 8)** ***Necessary Information to be Furnished by the Applicants for Licenses and Permits.*** **–** In the application of this Section, the PDEA shall require all license and permit applicants the following information:

(a) Exact quantity, or a reasonable approximation thereof if the exact quantity cannot be determined, of the Dangerous Drug or Controlled Precursors and Essential Chemicals intended covered by the transaction or activity;

(b) In relation to the above, the training and background of applicants and their personnel, including their employment of a Pollution Control and Safety Officer, whenever necessary, in the handling and disposition of Dangerous Drug and Controlled Precursors and Essential Chemicals

(c) in the case of transit or export, the specific address in the country of intended destination and identity of the consignee or ultimate recipient to which any such substance will be held in transit or exported to;

(d) Valid Certificate of Product Registration for Dangerous Drugs issued by the Food and Drugs Administration;

~~(c)~~(e) In case of an unregistered dangerous drug or device, a valid Compassionate Special Permit issued by the Food and Drugs Administration shall be provided in lieu of the Certificate of Product Registration;

~~(d)~~(f) any other relevant matter that the DDB or PDEA may

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prescribe or require whenever the circumstances may warrant.

Section 7(After Section 6). *Applicability for Licenses and Permits.* – Except pursuant to and in accordance with the terms and conditions of a license granted by PDEA, and unless previously authorized or permitted, no entity shall engage in any of the following activities:

(a) Cultivation of any plant source of dangerous drugs;

(b) Manufacture, importation, exportation, sale, trading, administration, transportation, transshipment, dispensation, prescription of any dangerous drugs or controlled precursors and essential chemicals;

(c) Conduct or undertake researches, laboratory analyses, trainings, studies, or other projects using any Dangerous Drug or Controlled Precursors and Essential Chemicals

Provided, the transfer or delivery of the Dangerous Drug or Controlled Precursors and Essential Chemicals from a license holder to another license holder, except retail sales, shall not be made except upon prior approval of the PDEA through a Local Purchase Order (Local Order Permit).

Section 8. *Local Order Permit.* – 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 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 officer of PDEA. Once approved, no request for alteration shall be allowed.

Provided, a Local Order Permit comes in duplicate copies: Copy 1 for the seller/supplier; Copy 2 for the applicant purchaser

Section 9.(Merge with Section 7)
***Independent Activities.* –** Unless specified otherwise, the following groups of activities are deemed to be independent of each other and shall have separate registration and license:

(a) Importation, for wholesale distribution or as industrial end-user
(b) Exportation
(c) Manufacturing
(d) Wholesale distribution
(e) Retail
(f) Storage of dangerous drugs or controlled precursors and essential chemicals in separate addresses
(g) Industrial use from local source
(h) Research, laboratory analysis, technical, teaching, or training program or project
(i) Trading

Section 10. *Registration of Business Addresses.* – An shall 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 at the same location shall secure from PDEA a license for each type of business. For this purpose, the PDEA shall issue a consolidated license detailing the type of activities and corresponding license.

Provided, however, that satellite pharmacies shall not be required to obtain separate licenses for each place of activity or business.

Section 11. *Accreditation and Authorization of Transporters, Haulers, Carriers, Couriers of Dangerous Drugs or Controlled Precursors and Essential*

Chemicals. **–** Entities engaged in the transportation, hauling, conveyance, and other analogous acts relative to the handling of dangerous drugs or controlled precursors and essential chemicals shall be subject to the same regulatory requirements set forth herein.

Provided, it shall be understood that the entities referred to in the preceding provision shall not be an integral part, subsidiary, conduit or affiliate, of a PDEA–licensed entity. Otherwise, the entity shall be exempt from securing a license and permit.

Provided, further, that any transporter, hauler, carrier, or any person engaged in a similar kind of activity which is an integral part, not a mere subsidiary, conduit or affiliate, of a customs brokerages firm registered with the Bureau of Customs or Philippine Export Zone Authority shall, likewise, be exempt from securing separate license and permit. However, such entity shall be accredited with the PDEA as an entity authorized to transport, haul, or carry from one place to another Dangerous Drugs and Controlled Precursors and Essential Chemicals, subject to the following requirements, whenever applicable:

(a) Authority to operate trucking company or certificate of public convenience from the LTFRB, Bureau of Customs, PEZA, and other government office of competent authority;

(b) Mayor's Permit/Business Permit;

(c) Articles of Incorporation, By-Laws, and SEC Certificate of Incorporation;

(d) NBI clearance of owner*,* proprietor, or corporate officers;

(e) Inventory of trucks or vehicles, which are intended to be used in the transportation, conveyance, or delivery of Dangerous Drugs or Controlled Precursors and Essential Chemicals, where the make, form, and plate numbers are indicated that will be used to transport controlled substances;

(f) Agreement or contract between the concerned parties where the provision of the security measures that will be undertaken to prevent diversion, loss, theft, pilferage and other analogous circumstances, among others, during the transport or delivery of DD or CPECS are stated;

(g) Industrial Technology Development Institute (ITDI)/Department of Science and Technology (DOST) Calibration Certificate/Test Report;

(h) Undertaking, made under oath, that the entity will strictly abide with the provisions of RA 9165 and other pertinent rules and regulations for the handling, delivery, conveyance, transportation, and other analogous acts, of DD and CPECS. Further, and shall make the ITDI/DOST Calibration Certificate/Test available for inspection by PDEA upon demand.

Provided, finally, that the Philippine Postal Office (PhilPost) and other licensed commercial couriers of parcels shall, likewise, exempt from securing a license, but shall be required to secure accreditation pursuant to the immediately preceding provision.

Section 12. ***Type of License and Corresponding Fees.*** **—** Unless specifically exempted under this Regulation and other special laws or charters, the required fees per year for the corresponding licenses are as follow:

Dangerous Drugs			
Item	**Type of License**	**Description**	**Annual Fee**
(i)	S-2 Prescriber	License to prescribe dangerous drugs or preparations in any form, except its preparations containing Norephedrine/Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].	P1,500.00

(ii)	S-3 Retail distributor/ Dispenser	License to sell, procure, acquire, deal in, dispense, and retail dangerous drugs or its preparations in any form, except preparations 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.	P2,000.00
(iii)	S-4 Wholesale distributor	License to sell, procure, acquire, deal in and distribute dangerous drugs or its preparations in any form, except preparations containing Norephedrine/Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].	P4,500.00
(iv)	S-5-I Importer	License to import specified (a) dangerous drugs or its preparations in any form, except preparations containing Norephedrine/Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000]; (b) in vitro diagnostic reagents, buffers and analytical standards, test kits containing dangerous drugs.	P7,500.00
(v)	S-5-C Manufacturer	License to manufacture specified dangerous drugs and its preparations in any form. The license, however, shall not apply to the compounding and filling of prescriptions in drugstores, clinics and hospitals. The licensee need not obtain another license of the same nature of activity for CPECs that will be used in the manufacture of DDs or its preparations. May procure, acquire scientific apparatus or controlled laboratory equipment for manufacture of DDs or its preparations. May distribute DDs or its preparations, but may not retail the same.	P10,000.00
(vi)	S-5-E Exporter	License to export specified dangerous drugs and its preparations in any form to foreign entities duly licensed or authorized by their respective countries or jurisdictions.	P7,500.00
(vii)	S-5-D Bulk depot/storage	License for bulk depot or storage of specified (a) dangerous drugs and its preparations in any form, except preparations containing Norephedrine/Phenylpropanolamine at doses 25 mg or below [OTC drugs, per BFAD AO 163, s. 2000].; (b) CPECs used in the manufacture of preparations; and when such address is separate and distinct from the office address of the license holder.	P7,500.00
(viii)	S-5-B Transhipper	License to bring into the Philippines in transit or transship Dangerous Drugs or its Preparations.	P7,500.00
(viii)	S-7 Broker	License to deal with or transact matters involving Dangerous Drugs or its	P2,500.00

		Preparations as brokerage firms, entities, or individual broker.	

Controlled Precursors and Essential Chemicals			
Item	Type of License	Description	Annual Fee
(i)	P-1 Retail distributor	License to sell, procure, acquire, deal in, specified CPECs or its preparations for retail purposes only.	P1,500.00
(ii)	P-3 End-User	End-user of specified CPECs or its preparations. Not authorized to resell the same. Authorized to purchase from local sources only.	P4,500.00
(iii)	P-4 Wholesale distributor	License to sell, procure, acquire, deal in specified CPECs and its preparations for wholesale distribution to licensees.	P4,500.00
(iv)	P-5-I Importer	License to import specified CPECs and its preparations. May distribute the same for which license was issued. May not distribute any substance for which license was not issued.	P7,5000.00
(v)	P-5-C Manufacturer	License to manufacture or recycle specified CPECs and its preparations. May distribute that substance or class for which license was issued; may not distribute any substance or class which are not licensed. May procure, acquire scientific apparatus or controlled laboratory equipment for manufacture of DDs or its preparations. May distribute CPECs or its preparations, but may not retail the same.	P10,000.00
(vii)	P-5-E Exporter	License to export specified CPECs and its preparations.	P7,500.00
(viii)	P-5-D Bulk depot/storage	License for bulk depot/storage of CPECs and its preparations if the address of which is separate and distinct from the office address of the licensee.	P7,500.00
(ix)	P-5-IM Importer/End-user	License to import specified CPECs or its preparations, as End-user. Acquisition of CPECs or its preparations shall be made through importation. The license holder is authorized also to acquire the same from local sources but is not authorized to resell them.	P7,500.00
(viii)	P-5-B Transhipper	License to bring into the Philippines in transit or transship Controlled Precursors and Essential Chemicals and its preparations.	P7,500.00
(viii)	P-7 Broker	License to deal with or transact matters involving Controlled Precursors and Essential Chemicals or its preparations as brokerage firms, entities, or individual broker;	P2,500.00

License to conduct laboratory analysis for scientific, medical, technical research, training, or other analogous purposes			
Item	Type of License	Description	Annual fee
(i)	S -6 or P-6 Research/ Analysis/	License to acquire, procure, import, export, manufacture, cultivate, for the purpose of conducting laboratory analysis	P1,500.00

	Instructional program	for technical research or instructional/training programs, including K-9 or X-ray, DDs and CPECS or their preparations. May procure or acquire syringe, scientific apparatus or laboratory equipment.	

Section 8. ***Application for Licenses.*** **—** An applicant shall submit a written application to PDEA with the following information:

(1) Full name, private and business address of the applicant;
(2) Each activity or transaction to which the application relates;
(3) If the applicant is a corporation, articles of incorporation, by-laws, SEC Certificate of Incorporation;
(4) If the applicant is a partnership, articles of partnership and SEC certificate of registration;
(5) If the applicant proposes to engage in the activity under a business name, that name;
(6) If the applicant is a sole proprietorship, DTI Certificate of Registration;
(7) If the applicant is a pharmacy, valid FDA License to Operate;
(8) If the applicant is a laboratory, valid DOH License to Operate;
(9) *If the applicant is a Medical Specialty Unit not situated within a Medical Institution, DOH License to Operate or FDA License to Operate;
(10) Generic~~Brand~~ name of the dangerous drugs or controlled precursors and essential chemicals to which the application relates and the address of each place where the proposed activity would be carried out;
(11) Premises where the dangerous drugs and controlled precursors and essential chemicals will be stored;
(12) Security arrangements that would be implemented at each address (storage, access, type of building construction, alarm systems, adequacy of supervision over employees having access, procedure of handling guest and maintenance personnel, adequacy of system for monitoring receipt), and the distribution and disposition of dangerous drug and controlled precursors and essential chemicals;
(13) Name, residential address and proof of authorization~~qualification~~ of each person under whose supervision the activity would be carried out:
(14) Whether the entity has ever been convicted in the Philippines or elsewhere for a serious offense or any offense however described relating to trafficking in dangerous drugs or controlled precursors and essential chemicals;
(15) Volume estimate in the forthcoming year and volume statistics for the past year of dangerous drugs; 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 the dangerous drug produced;
(16) Name of the brokerage firm or broker who handled the previous transactions of the applicant involving Dangerous Drugs or Controlled Precursors and Essential Chemicals and the details of the transactions.

(i) A plan of each of the relevant premises, indicating where the dangerous drug would be stored, and the location and nature of any security device(s);
(ii) Registration with the Philippine Export Zone Authority or Board of Investments, as applicable;
(iii) Business permit or certificate of registration issued by the local government unit, Department of Trade and Industry or Securities and Exchange Commission;
(iv) National Bureau of Investigation (NBI) clearance;
(v) The prescribed fee.

Section 13. ***Renewal of Licenses.*** **—** A license shall be renewed within three (3) months prior to the expiration of the same, subject to the completion of the requirements for registration. *Provided*, that any change in the category of activity or change in ownership shall

require a new license application.

For those who have stocks of DDs or CPECs, fFailure to renew within the said period would entail a penalty of Php 2,500 without prejudice to the filing of administrative and criminal cases for acts or transactions made after the expiration of the license, unless the same has been earlier surrendered, revoked, or retired.

Failure to renew within the said period would entail a penalty of Php 2,500 upon re-application for license (one time penalty? Or for every year of non-renewal?) without prejudice to the filling of administrative and criminal cases for: acts or transactions made after the expiration of the license and continued possession of DDs or CPECs

The failure of the licensee to make a tender or turn over of the license within five (5) days from the date of its expiration shall render the continued possession of DDs or CPECs illegal and the same shall be seized and confiscated, upon an inspection by the PDEA of the storage facility of the licensee, pursuant to REPUBLIC ACT NO. 9165, as amended by REPUBLIC ACT NO. 10640.

Section 14. ***Application for Import, Export, Transit, Transship, and Redirection Permit. —*** An application for an import, export, transit, or transship permit shall be made in writing by a licensee to the PDEA at least fifteen (15) working days before the intended date of arrival, departure, transit and transshipment takes place and specify:

(1) The full name and address of the importer, exporter, carrier, consignee, the ultimate consignee, and the broker, if any;
(2) In the case of a proposed import, export or transit of the dangerous drug, its generic name, and trade name or brand name, if any;
(3) The quantity, mass and volume of the dangerous drug; ~~Bd. Reg. on the Implementing Guidelines for the Implementation of Board Regulation No. 6, Series of 2007 5~~
(4) The date or period within which the planned import, export or transit is to take place;
(5) The planned transport route, if known, including the planned point of entry or exit from the Philippines; and
(6) In the case of proposed import of the dangerous drug to a bonded warehouse, the identity and exact address of the warehouse and a copy of the certificate or accreditation from the Bureau of Customs.

In the case of a proposed export of Dangerous Drug or Controlled Precursor and Essential Chemical, the import permit issued by the government of the foreign State of intended import shall be attached to the application for export permit.

Section 15. ***Grant of Import, Export, Transit, Transship, or Redirection Permits.*** The PDEA may, upon a valid and complete application made by a licensee, grant an import permit, export permit, transit permit, or transship permit in relation to a specified transaction involving the importation, exportation, transition, or transshipment transaction of a Dangerous Drug or Controlled Precursor and Essential Chemical within three (3) working days reckoned from the date of the submission of the said application. 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.

An approved import permit, export permit, transit permit, or transship permit is valid for a single shipment only. The PDEA shall not grant an export permit in relation to any shipment of a Dangerous Drug or Controlled Precursor and Essential Chemical 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.

An import, export, transit, transship, or redirection permit shall specify:

(1) the full name and address of the licensee and its broker;
(2) the name (including any international non-proprietary name and trade name), quantity, form, and packaging of any controlled substance for which it is granted;

(3) the original intended route of the shipment and its transshipment or redirection routes, if any;
(4) in the case of an import permit:
  a. the name and address of the exporter;
  b. the import is to be effected in a single shipment;
  c. intended international port of entry in the Philippines
(5) in the case of an export permit:
  a. the name and address of the immediate consignee, and if known, of the ultimate consignee;
  b. 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;
  c. the intended port of entry in the foreign State of import;
  d. if the export shipment is intended for an authorized bonded warehouse and is not prohibited, the shipment will be exported;
  e. the period during which the import or export is to be effected;
(6) the case of an intended import to a bonded warehouse, a term that:
  a. any subsequent withdrawal from the bonded warehouse shall require a permit from the PDEA; and
  b. if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;
(7) A permit to include a Dangerous Drug, except preparations 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 the PDEA.

In all cases of importations, exportations, transitions, and transshipments of Dangerous Drugs or Controlled Precursors and Essential Chemicals, the latest version of the Material Safety Data Sheet or Safety Data Sheet or globally harmonized system-based (GHS-based) of the substance should be submitted to PDEA, the Secretariat, DENR-EMB, and the Bureau of Customs.

Such other particulars, terms and conditions as PDEA may consider operationally necessary and reasonable may be stated in the permits.

Section 16. ***Duty of Brokerage Firms or Brokers.*** **—** ~~In lieu of the permit requirement,~~ ~~I~~the brokerage firm or broker handling the transaction covered by a license under this Board Regulation~~permit~~ shall furnish the Board, ~~not later than~~ atleast forty-eight (48) hours before the transaction, of the details of the transaction, attaching thereto copies of import or export documents, such as, but not limited to, the Master and House Bills of Lading, Correction Memoranda, Packing List, Manifest, Air Way Bills, and other documents analogous to the foregoing.

~~**Section 17**~~**.** ***Contents and Conditions of Licenses.*** **—** A license issued by the PDEA shall specify:

(1) The full name and address of the licensee;
(2) Each activity to which the license relates;
(3) The brand name and generic name of the Dangerous Drug to which the license relates;
(4) The name of the Controlled Precursor and Essential Chemical to which the

license relates;
(5) Threshold limits;
(6) The address of each place and premises at which:
    a. the covered activity is to be carried out; and
    b. the Dangerous Drug or Controlled Precursor and Essential Chemical are to be stored;
(7) Such terms and conditions are necessary and reasonable for ensuing the proper:
    a. carrying out and supervision of the licensed activity
    b. establishment, maintenance and preservation of record relating to that activity;
    c. reporting to the PDEA in relation to the carrying out of that activity;
(8) In the case of any license to import, export, bring to the Philippines in transit, or transship the Dangerous Drug or Controlled Precursor and Essential Chemical, the condition that a separate import, export, transit, or transship permit be first obtained in relation to any such transaction before it takes place; and
(9) Provision stating that the failure of the licensee to comply with the terms and conditions of the license or in case of a violation of the undertakings, the license is rendered *ipso facto* invalid or void;
(10) Official receipt number of prescribed fee.

Section 18. *Duration of Licenses and Permits.* — A license shall remain in force for one year, unless earlier surrendered, suspended, or revoked. A permit shall only remain in force for the specified duration of the particular transaction which in no case shall exceed three (3) months per transaction, unless a longer period is necessary for the accomplishment of the purpose of the permit, but in no case shall the same exceed six (6) months.

Section 19. *Grounds for Denial of Application for License*. — An application for a license registration may be denied by the PDEA upon a finding that the applicant:

(1) has materially falsified any application filed with the PDEA;
(2) has failed to comply with any of the entities obligation or undertakings;
(3) has been indicted or convicted of a crime under any law of any country relating to any DD and CPECS or any other serious crimes;
(4) had his PDEA license registration previously suspended or revoked;
(5) has pending administrative or civil or criminal case against him/her;
(6) has been convicted of any crime involving moral turpitude;
(7) has committed substantial or material violations of any of the Rules and Regulation issued by the Board;
(8) has failed to show adequate security for the storage of DD and CPECS;
(9) any of its corporate officers or incorporators has committed any of the foregoing.

Section 20. *Procedure for Denial of Application for License.* — PDEA within fifteen (15) working days after the submission of necessary documents and physical security inspection shall render a decision denying the application. The applicant shall be notified of the decision within five (5) working days after the decision is made.

The applicant whose application is denied may seek reconsideration with the PDEA, through its Legal and Prosecution Service. Within fifteen (15) days from receipt of the order denying the motion for reconsideration, an appeal may be made before the Dangerous Drugs Board Appeals Committee pursuant to Board Regulation No. 5 s. 2008.

Section 21. *Distribution and Retention of Permits.* — Copies of approved import, export, transit, transship, and redirection permits shall be distributed as follows:

(1) one copy for the exporter/supplier or the consignee of the importing country, as applicable;
(2) two copies for the Commissioner or the Collector of Customs of the port of entry, one of which is to be retained by the operator for customs clearing purpose and the other copy to serve as advance copy of the Bureau of

Customs;
(3) one copy for the competent authority of the country where the DD or CPECS is being imported or exported;
(4) one copy for the Philippine Embassy in the country where the importation, exportation, transition, transshipment, or redirection will be made;
(5) one copy for the PDEA.

Section 22. ***Acquisition of Emergency Medical Kits.*** **—** The acquisition of emergency medical kits for use in airplanes and vessels shall comply with the requirements set forth herein.

Section 23. ***Licenses and Permits in Relation to Laboratory Use, Programs for Medical or Scientific Research or Instructional or Training Purposes.*** **—** Licenses and permits may be granted to an applicant for the acquisition, procurement, importation, exportation, manufacture of Dangerous Drugs or Controlled Precursors and Essential Chemicals, or the cultivation of plant sources thereof, for the sole purpose of conducting laboratory analyses for technical research or instructional and training programs.

For purposes of this Section, the PDEA is hereby deputized and authorized to draft separate Standard Operating Procedures for the acquisition, procurement, importation, exportation, manufacture of Dangerous Drugs or Controlled Precursors and Essential Chemicals, or the cultivation of plant sources of dangerous drugs for:

(1) Scientific or Medical Research;
(2) Instructional or Training Purposes:
    a. DDs and CPECs Identification and Handling Training;
    b. Narcotics Detention Dog Training;
    c. X-Ray Training;
    d. Safety and Security Training on Hazardous Materials Handling; and
    e. Other analogous trainings.

The Standard Operating Procedure so drafted by the PDEA, endorsed by its Director General and with the conformity of the Director of its Legal and Prosecution Service, shall form part of this Regulation upon the approval of the Executive Director of the Board.

Section 25. ***Duty of Authorized Entities to Notify the Board of Material Changes.*** **—** Where, in relation to any license, permit, or authorization granted to an entity, a material change occurs in the:

(1) business name or address of the person, or its Chairman, President, Managers, partner, owner, Chief of Hospital, Hospital Administrator, Medical Director, partner, owner or any principal executive officer, brokerage firm or broker, or designated PDEA authorized pharmacist or signatory;
(2) address of the place or premises where:
    a. the licensed or permitted activity is carried out; or
    b. any DD or CPEC is stored;
(3) raw material for use in the manufacture or denaturing processes of any DD or CPEC;
(4) security arrangements implemented at any relevant address;
(5) identity of persons under whose supervision the licensed activity is carried out;
(6) planned transport route, including the planned date and point of entry or exit from the Philippines of any import, export or transit shipment for which a permit has been granted;
(7) quantities of DDs or CPECs 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; and
(8) status of the planned importation of the DD or CPEC.

the licensee shall, within five (5) working days from occurrence of a material change or (5) working days prior to arrival of the shipment, whichever is earlier, apply for an amendment of the permit or license before the PDEA, copy furnished the Secretariat. In no case shall an amendment be made to reflect a change in the type of DD or CPEC to be imported, exported,

transshipped, transited, or redirected.

Section 26. *Retirement and Discontinuance of the License Granted.* — A licensee who intends to cease operations, or cease prescribing dangerous drugs on a specified date prior to or until the expiry date of the license, shall notify the PDEA, copy furnished the Board, in writing at least sixty (60) working days prior to its intended date of secession.

The PDEA shall conduct a pre-retirement compliance inspection. The licensee shall make arrangements for the transfer of its stocks of DDs or CPECs to other licensees, or the surrender thereof to the Laboratory Service PDEA, until the approved date of cessation of license. The original copy of PDEA license and a properly accomplished and updated record of transactions shall be submitted to the PDEA within thirty (30) working days before the cessation.

All DDs or CPECs still not so transferred to other licensees shall be surrendered to the Laboratory Service of PDEA upon the date of cessation of license for proper and prompt disposition. The failure to surrender such stock shall be dealt with pursuant to the provisions of REPUBLIC ACT NO. 9165, as amended by REPUBLIC ACT NO. 10640.

Section 23. *Suspension or Revocation of License, Permit or Authorization.* — the PDEA, upon complaint or ***motu proprio***, may suspend or revoke licenses, permits, accreditations, or authorizations, as it deems necessary and reasonable under the prevailing circumstances, based on any of the following grounds:

(1) Failure to notify the PDEA and the Secretariat of a material change under Section 25;
~~(2)~~ The licensee or authorized entity or individual has a pending case or conviction for a drug offense before any tribunal and jurisdiction, or of other serious criminal offenses involving moral turpitude;
   a. The licensee or authorized entity or individual committed gross or repeated violations of any of the Resolutions or Regulations issued by the Board~~.~~
(3) the safety and security measures provided for the storage of DDs or CPECs are inadequate;

The proceedings for the suspension and revocation of licenses and permits shall be pursuant to the to the Rules of Procedure that the PDEA shall draft, subject to the approval of the Executive Director of the Secretariat upon the endorsement of the Director General of PDEA with the conformity of the Director of its Legal and Prosecution Service.

Section 24. *Duty of Operators to Check and Notify Suspicious Orders and Transactions.* — Whenever a licensee or authorized entity or individual has reasonable grounds to believe or suspect that the information that it has concerning the order or transaction may be relevant to an offense or a possible offense under REPUBLIC ACT NO. 9165, as amended, THE REVISED PENAL CODE, and other special penal laws, the same be shall promptly reported to the PDEA and the Board.

Section 25. *Prohibition against Advertising.* — Dangerous drugs or CPECs shall not be advertised or promoted in any platform available to the general public. It may, however, be advertised and promoted in medical or scientific journals, publications, literatures, and conventions solely intended for medical, scientific, or allied professions.

Section 26. *Prohibition against distribution of samples.* — Dangerous drugs or CPECs shall not be distributed as samples.

Section 27. *Prohibition on Tampering with DDs or CPECs.* — No entity shall cause a DD or CPEC lawfully in transit, or prior to its transit, to be subjected to any process which could alter its nature or otherwise than in accordance with instructions issued by the PDEA, or deliberately open or break any package or container containing the same. Any alteration, switching, tampering, and adulteration of the DDs or CPECs, contemplated herein, is prohibited.

No licensee shall, except under the authority of a redirection or transship permit, cause

any DD or CPEC, in transit to be redirected or transshipped to any other destination other than that shown on the import, export, redirection, or transship permit accompanying the DD or CPEC.

Section 28. *Prohibition on Counterfeiting of DDs and CPECs, Importation, Distribution, Manufacture, Dispensation, Trading, Administration, and Sale of Counterfeit DDs or CPECs. –* No entity shall counterfeit any DD or CPEC, import, distribute, manufacture, dispense, trade, administer, and sell counterfeit DDs or CPECs, or cause the doing of any of the foregoing acts in violation of REPUBLIC ACT NO. 10918 or REPUBLIC ACT NO. 8203.

Section 29. *Declaration in Commercial Documents. —* Any commercial document, such as an invoice, cargo manifest or a custom's transport and other shipping document, relating to any covered transaction by a licensee shall include:

(1) the name and quantity of the DD or CPEC;
(2) in the case of any import or export, the name and address of the exporter, the importer, the ultimate consignee, origin of the DD or CPEC, port of embarkation, port of debarkation, registered name of the conveyor, date of departure from origin, date of arrival and port of entry.

Section 30. *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 31. *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 32. *Notification, Endorsement and Return of Export Permits following Import*. — Upon the arrival of a shipment of DDs or CPECs in the country or place of intended exportation:

(1) the licensee granted the permit shall immediately report *(first notice)* to the PDEA the arrival of the subject shipment at the designated port of entry;
(2) 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 and ensure that all steps are taken so as to prevent the diversion of the controlled substance to an illicit market or use.
(4) 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;
(5) 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 a notation that the shipment did not arrive within ten (10) working days following the expiry date. Likewise, the importer must also notify the PDEA and the Board of the same.

Section 33. *Forwarding of Redirection and Transshipment Permits*. — Where a redirection or transshipment permit is duly issued:

(1) one copy shall accompany the controlled substance when it is exported from the Philippines;
(2) 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;
(3) one copy shall be retained by the operator;
(4) one copy shall be provided to the Collector of Customs of the port of entry/exit; and
(5) one copy is to be retained by the PDEA-CS for file.

Upon the issuance of such permit, the entity holding the export permit, redirection permit, or transshipment permit accompanying the DDs or CPECs upon its arrival in the Philippines shall remit it to the PDEA for verification who shall, thereafter, return it to the issuing authority~~,~~ together with an endorsement specifying the following:

(1) the name of the foreign country to which the shipment has been redirected or transshipped;
(2) the quantity of each DD or CPEC that was actually imported; and
(3) details of the change in the shipment route.

***The foregoing, in so far as applicable, shall apply to domestic redirections and transshipments

Section 34. *Limitation on the Stocks of Licensees.* — On or before the 31st of December each year, the Board, 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 DD or CPEC that may be manufactured or held in stock for the normal conduct of business during the following year.

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.

Article IV
SALE, SUPPLY, OR DISPENSATION FOR MEDICAL AND PHARMACEUTICAL USE

Section 1. Entities Authorized to Engage in the Sale, Supply, or Dispensation of Dangerous Drugs or *Preparations for Medical or Pharmaceutical Use.* — No entity shall engage in a conduct that constitutes the sale, supply, or dispensation of any dangerous drug, in any dosage form, unless a holder of a valid S-3 or S-4 license, or any of the following:

(1) a pharmacist employed by a licensed entity, who sells, supplies, or dispenses to another entity with a valid S-2 prescription;
(2) a trained nurse or pharmacy assistant under the immediate supervision of a pharmacist;

Section 2. *Contents of Prescriptions*. — A prescription for a dangerous drug or a preparation shall only be issued by an S-2 Licensee in favor of his or her patient, which he or she has physically examined, and shall conform to the following requisites:

(1) be on a Special Prescription Form, unless in emergency cases;
(2) be signed and dated by the prescribing practitioner on the date of issue;
(3) contain only one dangerous drug;
(4) be issued in triplicate copies with specific direction of use. The original copy of the 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 for 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;

(5) if the prescription is issued by an S-2 licensed veterinarian, the following information should be indicated:

a. the inscription "for veterinary use" on the face of the prescription;
b. the name, address and contact numbers of the owner or caretaker of the animal and the animal;
c. a means of identifying the animal, when applicable, such as electronic chips, tattoos, ear tags, name tags or collar, and other identifying marks;
d. species or breed, gender, and history of castration or spaying;
e. 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;
f. administration instructions and any relevant warnings; indicate gradual reduction of the medication;
g. diagnosis of the veterinarian signing the prescription; and

(6) The standard information to be supplied by the S-2 licensee in the prescription shall be:

a. the complete name;
b. complete business address;
c. contact number;
d. current S-2 License number and validity of license;
e. Professional Tax Receipt of the prescribing practitioner; and
f. original signature

(7) The patient's standard information be supplied by the S-2 licensee in the prescription shall be

a. Complete name;
b. Age;
c. hospital room number or complete address of the patient;
d. date of the prescription;
e. generic and brand name of the dangerous drugs to be supplied, its dosage strength, frequency, route of administration, dosage form and the total number of dosage units or total quantity of preparation to be supplied in words and its numerical equivalent, commensurate to the therapeutic needs of the patient;
f. direction of use, and Direction of use must be clearly and completely specified. "Take as directed" or "Take as required" is not authorized.

Section 3. ***Pharmaceutical Equivalents.*** **–** In the event that only the generic name is written on the prescription it is upon the discretion of the pharmacist in charge to dispense any pharmaceutical equivalent that is readily available in the pharmacy.

Where the brand name or the dosage strength indicated in the prescription is not available, the pharmacist shall call the physician for the purpose of conferring with the latter the propriety or disposition relative to the matter. Thereafter, the pharmacist shall reflect on the face of the prescription the matters agreed upon.

Section 4. ***Duty of Pharmacist*** **—** Whenever the quantity prescribed in a prescription has been fully dispensed by the drugstore, such fact shall be indicated by the pharmacist by stamping "**FULLY DISPENSED**" in bold prints across the original copy of prescription.

Provided, in case the quantity has not been fully dispensed, the inscription "**QUANTITY DISPENSED**" should be clearly indicated on the face of the prescription stating therein the balance in words and its numerical equivalent and countersigned 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.

Provided, further, that the pharmacist shall follow the order and instruction of the medical practitioner 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 medical practitioner for verification.

Provided, furthermore, that a pharmacist shall not supply a dangerous drug on presentation of a prescription, if she/he knows or has reason to believe that the prescription or order was:

(1) issued more than thirty (30) days before presentation. Nonetheless, in the case of a multi-month prescription, a ninety (90)-day period shall apply, which shall be reckoned from the date indicated by the medical practitioner;
(2) already terminated by the discontinuance of the medication by the prescriber or death of the patient;
(3) the prescription is outside the scope of practice of the medical practitioner;
(4) incomplete, illegible, improperly prepared, improperly signed, or shows any signs of alteration, forgery, erasure, or fraud;
(5) Other circumstances analogous to the foregoing.

Provided, finally, that in a community setting or Out-Patient Pharmacy, the dispensing pharmacist shall require the person who will receive the drug to indicate his/her complete name, and address, valid government-issued identification card with picture, or in case of foreigners, present the original or photo copy of passport and affix signature at the back of the prescription.

Section 5. ***Prescription Limitations for Human Use.*** **—** An S-2 Licensee shall only prescribe dangerous drugs, using a Special Prescription Form, that are commensurate to the therapeutic needs or requirement of the patient which he or she has personally and physically examined, assessed, and diagnosed

Provided, where there is a need for a longer duration of the therapy, the S-2 Licensee may prescribe dangerous drugs for a maximum of thirty (30)-day supply per prescription.

Provided, moreover, in cases of *epilepsy* and *dystonia*, the S-2 Licensee may prescribe dangerous drugs for a period exceeding thirty (30) days.

Provided, furthermore, that the S-2 Licensee involved in palliative and hospice care shall indicate a specific length of therapy or number of doses in the individual patient's order, which shall not exceed one (1) week supply. In homes where the patient is under the palliative and hospice care, the administration of dangerous drugs may be designated to a well-trained health practitioners under the supervision of the S-2 Licensee who prescribed the dangerous drugs.

Finally, under no circumstance, however, shall an S-2 licensee issue a prescription to any individual for the purpose of acquiring DDs for his own use, for the use of another individual other than the named patient, or disposal by any other means.

Section 6. ***Provision for DDs in Emergency Bags of Medical Practitioners.*** **–** Medical Practitioners who are S-2 Licensees may possess or carry with them in their emergency bags DDs in quantities that are only (quantity issue)

the quantity of which shall be not to exceed allowed by the Board for administration and treatment to a home care patient.

A medical practitioner planning a treatment option of a patient who has pain from cancer, or intractable pain, or pain as a result of terminal illness, or any ailment requiring a DD or its preparation, shall ensure that such 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:

(1) a recognized medical indication for the use of the dangerous drugs;
(2) the generic and brand name of the dangerous drugs
(3) the dosage, strength, and quantity of the dangerous drugs;
(4) specific instructions to the patient about frequency of use; and
(5) patient response to the treatment.

A practitioner shall remain alert to the possibility that a 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.

Section 7. ***Issuance of Prescription in Favor of a Drug Dependent.*** **—** A prescription shall not be issued for the dispensing of DDs or its preparations in favor of a drug-dependent, unless the S-2 licensee is, likewise, duly accredited with the DOH to conduct a treatment program, and under the following conditions:

(1) To relieve acute withdrawal symptoms, provided that:
    a. such treatment does not exceed seventy two (72) hours;
    b. not more than (one) 1-day's supply of the drug is provided to the patient at a time; and
    c. arrangements are made for referring the patient to a drug treatment program for treatment.
(2) As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility."

Section 8. ***Prescription Limitations for Veterinary Use.*** **–** An S-2 Licensed Veterinarian may only prescribe a dangerous drug for veterinary use under the following circumstances:

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

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

Section 9. ***Storage and Stock of Dangerous Drugs.*** **–** Only S-3 Licensees may store and stock DDs in accordance with pertinent regulatory measures or regulations relative to the handling, custody, safekeeping, and storage of DDs.

Section ____. ***Issuance and Handling of Prescription of Dangerous Drugs.*** **–** An S-2 licensee medical practitioner shall issue prescriptions in Special Prescription Forms in one (1) original and two (2) duplicate copies. The original, after the prescription has been filled, shall be retained by the pharmacist for a period of one (1) year from the date of sale or delivery of such drug. One (1) copy shall be retained by the buyer or by the person to whom the drug is delivered until such drug is consumed, while the second copy shall be retained by the person issuing the prescription.

For purposes of this Regulation, in accordance with REPUBLIC ACT NO. 9165, as amended by REPUBLIC ACT NO. 10640, section 40, all prescriptions issued by S-2 licensees shall be written on Special Prescription Forms exclusively issued by and obtainable from the DOH. Such forms shall be made of a special kind of paper and shall be distributed in such quantities and contain such information and other data as the DOH may, by rules and regulations, require. Such forms shall only be issued by the DOH through its authorized employees to licensed physicians, dentists, veterinarians and practitioners in such quantities as the Board may authorize. ~~In emergency cases, however, as the Board may specify in the public interest, a prescription need not be accomplished on such forms. The prescribing physician, dentist, veterinarian or practitioner shall, within three (3) days after issuing such prescription, inform the DOH of the same in writing.~~ No prescription once served by the drugstore or pharmacy be reused nor any prescription once issued be refilled.

Section _____. *Issuance and Handling of Ordinary Prescription of Dangerous Drugs in Emergency Cases.* – In emergency cases, as defined and described in this Regulation, the issuance of dangerous drugs using ordinary prescription forms may be allowed only for initial dosing or initial treatment to promptly address the emergency.

Provided, upon the alleviation of the symptoms or severe pain of the patient, the S-2 Licensee shall promptly cause, within twenty-four (24) hours, the issuance of a prescription using the Special Prescription Form indicating therein the particulars of the dangerous drugs prescribed and administered to the patient during an emergency case.

Provided, further, that the ordinary prescription earlier issued shall be consolidated with the Special Prescription Form and shall form part of the report for submission to the PDEA.

Provided, finally, that the pharmacists who dispensed dangerous drugs during emergency cases shall indicate in the registered record book the reason or emergency that warranted the dispensing of such substance under such circumstances.

Section 10. *~~Procurement~~ Acquisition of Special Prescription Forms*. — an S-2 licensee may ~~purchase~~ acquire at the most ten (10) booklets of special prescription forms at a time from any government ~~the DOH~~ hospitals or DOH-designated ~~or its~~ official distribution sites. Provided, an S-2 licensee may only possess a maximum of 10 booklets at a single time.

Provided, Special Prescription Forms and booklets shall not be sold or distributed for a fee or any other monetary consideration in both public and private sectors.

Special Prescription Forms are non-transferrable and accountable forms. These shall be for the exclusive use of the S-2 licensee, which shall be valid for the duration of the S-2 license, and shall be used consecutively according to its serial number.

All unused Special Prescription Forms for dangerous drugs shall be immediately surrendered to any government hospitals or DOH official distribution sites ~~DOH or its official distribution sites~~ under any of the following circumstances:

(1) departure for any place outside the Philippines, if the period of stay therein is more than six months;
(2) cessation of, or retirement from, practice;
(3) non-renewal of PDEA S-2 license;
(4) death – the surrender of the special prescription forms for dangerous drugs may be done by the nearest kin of the deceased practitioner to whom such forms were issued; and
(5) in any case, the DOH or its authorized representatives shall issue an acknowledgment receipt for the surrendered special prescription forms for dangerous drugs.
(6) The licensed practitioner shall keep the used prescription booklets in a separate file in such manner as to be readily accessible to inspection by PDEA, for a period of one year.

In furtherance of the foregoing, the Department of Health shall ensure that there is sufficient supply of special prescription forms for human use and for veterinary use.

Section 11. *Requisitions, Dispensing and Administration in Hospitals/Institutions for Purpose of Treatment.* — No entity shall issue a requisition for a dangerous drug unless the he or she is an S-2 Licensee.

Only a pharmacist, who must be a regular employee in a medical institution**,** can issue and dispense a supply of dangerous drugs to satellite pharmacies and floor stocks of such medical institution.

*Provided, s*atellite pharmacies are allowed to maintain stocks of dangerous drugs under the following circumstances:

a. The central pharmacy is an S-3 Licensee;
b. The inventory of its stocks shall be recorded and reported similar to floor stocks
c. Floor stocks shall only be replenished using stocks from the central pharmacy;

Section 12. 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 a 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 the 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 a controlled chemical (for incoming and outgoing passenger not exceeding thirty (30) days supply);

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

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

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

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

Section 13. *Exemption of Entities from Payment of Fees.* – The following entities shall be exempt from paying the license and permit fees:

1. Medical institutions owned or managed by the government;
2. State universities, colleges, or schools;
3. Full-time medical practitioners in active government service;
4. Government offices or agencies.

Section 14. *Dangerous Drug and CPEC Registers.* – All registered, licensed, accredited, or authorized entities shall maintain registers pursuant to REPUBLIC ACT NO, 9165, as amended by REPUBLIC ACT NO, 10640, section 40. In addition thereto, the said entities shall, likewise, comply with the following:

(1) A person who makes entry in a register shall only be the authorized person of the company and must register online.

(2) Any person required by this Section to keep a register shall, subject to any written direction to the person by PDEA, retain possession of the register and commercial documents relating to entries therein for two (2) years after the date of the last entry in the register. A 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.

(3) 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.

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

(5) Organizational members of Palliative and Hospice Philippines Inc. and other organizations shall comply with the reportorial requirements;

Section _____. *Submission of Semi-Annual Report to PDEA.* – 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 by licensed, registered, accredited, and authorized entities to DDB within fifteen days (15) days following the last day of June and December of each year using RCMIS.

Licensed retailers and users for laboratory use/or programs for medical, scientific research or instructional/training purposes shall submit semi-annual report as prescribed herein.

Section 17*. 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 request for a re-issuance of S2 License certificate upon submission of the notarized affidavit of loss and pay the corresponding replacement fee amounting to three hundred pesos (P 300.00).

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

The PDEA shall conduct an investigation to determine whether the incident was deliberately or negligently caused by the licensee. In the event the same was not due to any fault from the licensee, the issuance of a copy of the license or permit, where the fact of reissuance is made to appear on its face, and registers and special prescription forms shall be had.

The licensee shall cause the publication of a notice in a newspaper of general circulation, for two (2) consecutive weeks, such fact of loss with a warning not to honor any transaction using the lost license, permit, register, or special prescription form, indicating the serial number of the same whenever applicable.

Article V
SAFEKEEPING, STORAGE, DESTRUCTION, and DISPOSAL OF DDs and CPECs

Section 1. ***Safekeeping and Storage and Transporting of DDs and CPECs****.* — All licensees under this Regulation shall be responsible for all aspects of the safekeeping and secure storage and handling of DDs, CPECs and their preparations, chemical mixtures or their finished products containing controlled chemicals.

In a hospital setting, the dangerous drug placed or kept inside the code carts shall be provided with at least single lock for immediate access during emergency cases.

The licensee shall ensure that the safekeeping and handling of the DDs and CPECs, and their preparations, chemical mixtures or their finished products containing controlled chemicals are in accordance with the requirements defined in their Material Safety Data Sheet and in accordance with DDB prescribed guidelines on safekeeping, storage, use and transport and with the JOINT DTI-DENR-DA-DOF-DOH-DILG-DOLE-DOTC ADMINISTRATIVE ORDER NO. 01 Series of 2009.

Section 2. ***Disposal of DDs and CPECs.*** **—** In case of Dangerous Drugs:

(1) All licensed entities 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.
(2) In cases where the disposal of dangerous drug will be through a destruction facility, the facility shall be DENR-registered and compliant with the prescribed manner of disposal. It shall notify the 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.
(3) 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 portion and volumes of infusions; and unopened or out of date products shall be disposed immediately. Such disposal shall be witnessed by a trained nurse under the instruction of a pharmacist and documented in an appropriate form provided by the medical institution. The disposal of the unused drug and empty ampules and vials shall be in accordance with existing regulations issued by the DENR or other agency of competent authority.
(4) Medication returns for unused stock of dangerous drugs shall be in accordance with existing laws and regulations of the Department of Trade and Industry and other regulatory agencies: Provided, that patient safety shall at all times be of paramount consideration.
(5) The pharmacist at all times, should be responsible for the quality of medications that has to be dispensed. If the quality and integrity of the medications to be returned are questionable, this should not be accepted for the purpose of dispensing it to another patient.
(6) Disposal of expired dangerous drugs. Every month, the hospital pharmacy shall notify the PDEA of all expired dangerous drugs and preparations 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.

(7) 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.

In the case of Controlled Precursors and Essential Chemicals:

(1) All licensees that have an inventory of expired, or damaged, or contaminated CPECs or its preparation for disposal shall notify the PDEA Laboratory Service or PDEA Regional Office in writing for their intention to surrender the chemicals**.** Where the quantity is substantial, and after due inventory and recording by PDEA, the concerned licensee shall make arrangements for the transfer of the chemicals directly to a DENR registered chemical disposal company. The licensee shall bear the costs of the disposal by authorized means. Upon the disposal thereof, a copy shall be submitted to PDEA and to the Board for notation in the Controlled Chemical Register.
(2) A licensee disposing waste material containing CPECs or its preparations shall check whether the DENR-registered waste disposal company recycles the waste chemical for its chemical content, and, if it does, a PDEA license as a recycler shall be sought.

Section 4. ***Duties Where There is Loss or Theft of DDs of CPECs. —*** Where A loss in the whole or part of a shipment occurred while in transit to its ultimate destination, the transporter or hauler shall render a report to PDEA within twenty-four (24) hours from the discovery. Where discrepancy is discovered while the shipment is in the process of acceptance, the receiver shall render a report and also inform PDEA. In any case, where the shipment is not yet fully accepted by the recipient, the security of and accountability for the shipment while in transit to its ultimate destination shall remain as the responsibility of the entity or individual where the same originated and the transporter or hauler.

A licensed manufacturer, importer, exporter, or distributor of DDs or CPECs that are volatile in nature shall install an 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 the total annual inventory.

Section 5. ***DDs and CPECs Containers and Labeling and Relabeling Requirements. —*** Dangerous Drugs and Drug Preparations containing a Controlled Chemical shall conform with the Food and Drug Administration requirement on packaging, labeling and relabeling.

Manufacturers, suppliers, or distributors of DDs and CPECs shall ensure that the same are 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 substance until such time that the GHS-SDS will have become the effective standard SDS.

The containers should have the labels of the importer, exporter, manufacturer, and distributor, indicating at the minimum, the following information

(1) the product name as stated on the MSDS or Safety Data Sheet
(2) Identity and concentration of chemical components
(3) Danger markings; safety precautions
(4) Risks associated with the use of the chemical and first aid steps
(5) Details of manufacturer/importer and address and emergency contact number
(6) MSDS or Safety Data Sheet number, reference that MSDS or SDS is available.
(7) Importer's/Manufacturer's/Distributor's Lot or Batch Number
(8) English name of the substance;
(9) the batch number with unit (drum/carbouy/pail) number and name of seller

Said markings shall not be removed or wiped out unless the content is consumed and the subject container shall be reused. The container shall not contain any substance other than the substance so marked thereon;

Where an empty labeled container that previously contained a controlled chemical may be sold to another, but only upon notice to the Compliance Service and an inspection has been conducted of the same, 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 VI
APPOINTMENT, DUTIES, AND FUNCTIONS OF THE DANGEROUS DRUGS REGULATIONS OFFICERS

Section 1. ***Appointment/Designation of Regulatory Compliance Officers.*** **—** The Director General, PDEA shall appoint, designate and/or assign qualified and trained PDEA personnel, preferable those appointed Dangerous Drugs Regulation Officer and Drug Enforcement Officer positions, as Regulatory Compliance Officer.

Section 2. ***Inspection on Authorized Premises and Operations.*** **—** A PDEA licensee shall, when required by a visiting Regulatory Compliance Officer, open the registry record book for dangerous drugs and/or controlled precursors and essential chemicals. Such entity shall provide in writing the PDEA officer a statement signed and dated by that entity stating therein the account for each dangerous drug or controlled chemical from the time the PDEA license and or permit was granted.

Section 3. ***Duties of PDEA Regulatory Compliance Officers.*** **—** A person designated or assigned as a PDEA Regulatory Compliance Officer by the Director General, PDEA, and armed with a Mission Order, may, at any time during ordinary business or professional hours of the practitioner or operator enter any premises or place where any activity is carried out by the licensee in accordance with the license provided by PDEA.

Under urgent circumstances, such as when a backtracking investigation is being made for suspected chemical diversion or pursuant to an information held by PDEA that violations of the Act or this Regulation were made by the person, the Regulatory Compliance Officer may inspect the premises of the property at any time of the day or night. In such case, the Regulatory Compliance Officer shall be armed by a Mission Order signed by the Director General or the duly-designated *Officer-in-Charge* of his office.

A Regulatory Compliance Officer who enters any premises or place pursuant to this Article shall:

(1) require the occupant of the premises to supply his or her name and address and exhibit proof of identity;

(2) 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;

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

(4) 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;

(5) take photographs or video footages of the controlled substance and container and premises where it is stored;

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

(7) 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;

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

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

(10) examine to determine that the stocks of controlled substances are stored in an appropriate and secured facility;

(11) 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;

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

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

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

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

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

(17) access records of personnel involved in the handling of controlled substances.

(18) 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.

The Regulatory Compliance Officer shall see to it at all times that the dangerous drugs and controlled precursors and essential chemicals are monitored and accounted from its procurement or manufacture to its disposal pursuant to a *Cradle-to-Grave Approach.*

Section 4. *Obstruction of Regulatory Compliance Officer.* — No person shall, without reasonable grounds, by act or omission:

(a) Obstruct, hinder, or refuse the entry of a Regulatory Compliance Officer in the performance of his duties under this Regulation and other pertinent Board issuances;

(b) Refuse or fail to promptly comply with a valid request of a Regulatory Compliance Officer who has entered any premises in accordance with RA 9165 and this Regulation and other related Board Issuances within a reasonable period of time after such request.

ARTICLE V.
NATIONAL SUPPORT UNITS FOR THE ENFORCEMENT OF BOARD REGULATIONS

Section 1. *Interdiction Service.* — An Interdiction Service is hereby established,

which shall be organized and structured by PDEA as a national service, whose mandate is to intercept and prevent the unlawful entry and movement of any dangerous drugs and controlled precursors and essential chemicals. It may also recommend and supervise the conduct of controlled delivery operations pursuant to DDB REGULATION NO. 2, series of 2002.

The Interdiction Service shall be stationed at the National Headquarters of PDEA and shall hold stations in every airport and seaport in the Philippines. In the interest of public service, it may hold stations in other areas or establishments.

It shall be properly equipped with the necessary tools and instruments that may be necessary in the performance of its mandate. A Regulatory Compliance Officer shall, likewise, be assigned in every station of the said service.

Section 2. *Special Enforcement and Investigation Unit. —* a Special Enforcement and Investigation Division, under the Legal and Prosecution Service, is hereby created, which shall be the office of primary jurisdiction to investigate and institute cases for violations of Regulations issued by the Board, among others, and cause the prosecution of the same.

The Legal and Prosecution Service, through its designated Special Prosecutors, shall prosecute the cases so instituted from the start until its termination and shall submit to the Board an annual report on the status of cases filed for violation of Regulations issued by the Board.

The Compliance Service shall promptly transmit and endorse to the Special Enforcement and Investigation Division its report on fact-finding inquiries conducted to gather evidence against persons suspected of violating the provisions of this Regulation and other Regulations promulgated by the Board.

Section 3. *Controlled Substances Unit. –* For a more efficient accomplishment of the purposes or objectives of this Regulation, a Controlled Substances Section is hereby created to perform the following functions:

(1) Receive, evaluate and process the application for exemption from some regulatory control measures.
(2) Receive, evaluate and process the application for non-controlled, non-scheduled substances.
(3) Conduct monitoring inspection of DDB-registered entities
(4) Assist committees created by the DDB.
(5) Conduct studies on dangerous drugs, controlled precursors and essential chemicals including new psychoactive substances in coordination with other regulatory government agencies.
(6) Conduct orientation seminars to stakeholders and other interested parties relative to the Board resolutions, regulations, and other issuances.
(7) Receive, gather, collect and evaluate data pertaining to dangerous drugs and controlled precursors and essential chemicals and submit a report to the International Narcotics Controlled Board (INCB).
(8) Serve as an a INCB focal point.
(9) Performs others tasks as assigned by the Board

The Controlled Substances Unit shall be headed by a Pharmacist VI as the Unit Chief and assisted by two (2) Pharmacist V and four (4) Pharmacist IV. The Secretariat is hereby authorized to provide an organizational structure of such unit, adding as many personnel as it deems necessary for the accomplishment of its functions and duties.

Provided, that the Controlled Substances Unit shall be under the administrative control and supervision of the Legal Affairs Division of DDB, which shall, likewise, be restructured and reorganized as the Office of Legal Affairs and be comprised of the following:

(1) Division Head – Attorney VI
(2) Assistant Division Heads – Two (2) Attorney V
(3) Members – Six (6) Attorney IV
(4) Other personnel the Board may deem appropriate and sufficient for the accomplishment of its duties and functions.

Provided, finally, that nothing in this Regulation shall prevent the Board from adding or removing positions in the organizational structure of the Board.

ARTICLE VI
MISCELLANEOUS PROVISIONS

Section 1. *Penal Sanction. —* any person or entity found by PDEA to have violated this Regulation and previous issuances by the Board shall be dealt with pursuant to the penal provisions in **REPUBLIC ACT NO. 9165, as amended by REPUBLIC ACT NO. 10640.**

Section 2. *Repealing Clause. —* Board Regulations No. 3 – Series of 2003, No. 5 – Series of 2006, 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.

Section 3. *Separability Clause. –* In the event any of the provisions in this Circular is declared invalid, the remaining provisions not declared as invalid shall continue to be in full force and effect.

Section 4. Effectivity. – This Regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation and registration with the University of the Philippines—Office of National Administrative Regulations, UP Law Center, Quezon City.

Done in Quezon City this ___ day of _____, 2019.