

# PHILIPPINE MEDICAL ASSOCIATION

THEME: "BUILD, BUILD, BUILD PMA!"

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Confederation of Medical Association in Asia and Oceania (CMAAO)

Medical Association of Southeast Asian Nations (MASEAN)

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## MEMORANDUM CIRCULAR NO: 2018-10-03-031

TO

: PRESIDENTS OF: COMPONENT SOCIETIES, SPECIALTY DIVISIONS, SUB-SPECIALTY SOCIETIES, AND AFFILIATE

**SOCIETIES** 

DATE

: OCTOBER 3, 2018

SUBJECT

: GUIDELINES IN PRESCRIBING DANGEROUS DRUGS

Greetings from the Philippine Medical Association!

The Regulatory Compliance Officers of the Philippine Drug Enforcement Agency has called our attention regarding practices of some medical practitioners which do not conform with the prescribed reglementary requirements.

Among some of the observations that were noted as follows: prescribing practitioner not indicating his/her contact number which is relevant when a dispensing pharmacist verifies some information from the physician; incorrect S-2 license number indicated in the prescription; incomplete patient information as regards age and complete address; not indicating the quantity of the prescribed dangerous drug in words; all three (3) copies of a set of a prescription are given to the patient which is wrong since a prescriber has to retain one (1) copy for his/her file; not indicating the number of prescription issued to the patient in multi-month prescriptions for Schedule IV drugs of the 1971 UN Convention, etc.

In line with this, the PDEA is reminding our medical practitioners regarding the Guidelines in Prescribing Dangerous Drugs, written in Section 31 Article III of Board Regulation No. 1, Series of 2014, as per attached. The said regulation may also be downloaded at their website: <a href="mailto:pdea.gov.ph">pdea.gov.ph</a> or <a href="mailto:ddb.gov.ph">ddb.gov.ph</a>.

For your guidance and strict compliance to avoid future violation. Thank you.

Very truly yours,

BENJAMIN M. ALABAN, MD

Secretary General

Noted by:

JOSÉ P. SANTIAGO, JR., MD

President

Ref. No. 419/CS-Misc/2018

September 17, 2018

Jose P. Santiago Jr., MD President 2/F PMA Bldg., North Avenue, Quezon City 1105

## Dear Dr. Santiago:

This refers to Guidelines in Prescribing Dangerous Drugs. During the conduct of compliance inspections to PDEA-registered drug establishments, our Regulatory Compliance Officers (RCOs) noted that there are practices of some medical practitioners which do not conform with prescribed reglementary requirements.

Among some of the observations are: prescribing practitioner not indicating his/her contact number which is relevant when a dispensing pharmacist verifies some information from the physician; incorrect S-2 license number indicated in the prescription; incomplete patient information as regards age and complete address; not indicating the quantity of the prescribed dangerous drug in words; all three (3) copies of a set of a prescription are given to the patient which is wrong since a prescriber has to retain one (1) copy for his/her file; not indicating the number of prescription issued to the patient in multi-month prescriptions for Schedule IV drugs of the 1971 UN Convention and etc.

Hence, we would like to call your attention as regards Section 31 Article III of Board Regulation No. 1, Series of 2014 which specifically deals on "Prescriptions". See attached. Said Regulation can be downloaded in our website: pdea.gov.ph or ddb.gov.ph.

In this connection, may we request your association to disseminate this vital information to all your S-2 licensed medical practitioners for their guidance and reference to avoid future violation.

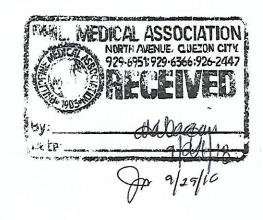
Your favorable consideration on this request is highly appreciated.

Truly yours,

AARON N AQUINO
Director General

Encl.: as stated





(www.pdea.gov.ph)
A second
Fentanyl Morphine Oxycodone Pethidine Methylphenidate Remifentanil
Buprenorphine Pentobarbital
Alprazolam Bromazepam Clonazepam Clorazepate Diazepam Midazolam Phenobarbital Phentermine Zolpidem
Ephedrine Ketamine Nalbuphine

- (c) a medical practitioner who, in accordance with the norms and standards of his or her profession:
  - (i) administers the drug directly to a patient or animal in the ordinary course of treatment; or
  - (ii) supplies the drug to a patient or an animal in the ordinary course of treatment from a place more than a five (5) kilometer-radius from the place of business of a pharmacy or within a five (5) kilometer-radius where there is no pharmacy store dispensing dangerous drugs and/or drug preparations containing controlled substances.

#### Section 31. Prescriptions

- (1) No person shall prescribe a dangerous drug or drug preparation, in any dosage form, which requires a valid 5-2 license, unless that person is a medical practitioner;
  - (a) who prescribes the drug in the ordinary practice of their respective profession
    - Physician
    - Dentist
    - Veterinarian
  - (b) granted an S-2 license to prescribe such drugs by the PDEA.
- (2) A prescription for a dangerous drug shall
  - (a) be on a Special Prescription Form unless specifically exempted;
  - (b) be signed and dated by the prescribing practitioner on the date of issue;
  - (c) contain only one dangerous drug and/or drug preparation containing a controlled chemical:
  - (d) 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;
  - (e) if the prescription is issued by a veterinarian, the following information should be indicated:
    - (i) the inscription "for animal use" on the face of the prescription;
    - (ii) the name, address and contact numbers of the owner or caretaker of the animal. The
      name and address of the person who will receive the drug if not already detailed earlier,
      shall also be handwritten;
    - (iii) the species of the animal;
    - (iv) a means of identifying the animal such as electronic chips, tattoos, ear tags, name tags/collar, and other identifying marks;
    - (v) Address of the premises where the animal is kept if different to that above;
    - (vi) The total quantity of medication in words and figures in the hand writing of the person prescribing the medication, including the dosage strength and number of dosage units;
    - (vii) administration instructions and any relevant warnings; indicate gradual reduction of the medication;
    - (viii) diagnosis of the veterinarian signing the prescription; and
    - (ix) In the case of a prescription for a dangerous drug in parenteral form which is directed to be administered more than once, the time interval between repeat administering.

- (3) The standard information to be supplied in the prescription shall be: the full name, complete business address, telephone number/email address, current S-2 License number and validity of license, and Professional Tax Receipt of the prescribing practitioner; complete name, age, and complete address of the patient, date of the prescription, generic and brand name of the preparation to be supplied, its dosage strength and form and the total number of dosage units or total quantity of preparation to be supplied in words and its numerical equivalent; direction of use, and the inscription "no refill" at the face of the prescription, and the original signature of the medical practitioner. Direction of use must be specified. "Take as directed" or "Take as required" is not authorized.
- (4)(a) No prescription, once filled by the drugstore or pharmacy shall be refilled.
  - (b) Whenever a prescription for dangerous drugs is filled up by the drugstore, it shall be the duty of the drugstore owner/pharmacist to cause the inscription "USED IN FULL" to be stamped in bold prints across the original copy of said prescription in case the full quantity of the drug therein stated is sold or dispensed and the inscription "USED FOR [dosage/units]ONLY" in case the quantity of the drug therein stated is not fully dispensed." The balance should be clearly indicated at the face of the prescription in words and its numerical equivalent and signed by the dispensing pharmacist. The pharmacist shall not reduce the quantity specified in the prescription unless by reason of lack of stock of the drug or the prescription holder asks for the reduction in quantity due to budgetary constraint. The dispensing pharmacist shall affix his/her signature at the face of the prescription and shall be made accountable for any violation that may be committed.
  - (c)The pharmacist shall follow the order and instruction of the physician as written on the prescription unless the pharmacist has sufficient reason to question the validity of the prescription, in which case the pharmacist shall contact the prescribing practitioner for verification.
- (d)A pharmacist shall not supply a dangerous drug and/or drug preparation containing a controlled chemical on presentation of a prescription, if she/he knows or has reason to believe that the prescription or order was:
  - forged, unlawfully altered, or cancelled; in which case the pharmacist shall contact the prescribing practitioner for verification.
  - (ii) issued more than sixty (60) days before presentation, except that for multi-months
    prescription, the sixty (60) days shall be based on the date indicated by the practitioner
    when the drug shall have been obtained;
  - (iii) already terminated by the discontinuance of the medication by the prescriber or death of the patient;
  - (iv) the prescription is outside the scope of practice of the prescriber;
  - (v) not complete, legible, properly prepared, properly signed, or shows any signs of alteration or erasure.
- (e) The dispensing pharmacist shall require the person who will receive the drug to indicate his/her complete name, and address, valid government-issued identification card with picture, or in case of foreigners, present the original and photo copy of passport or any valid government-issued identification card and affix signature at the back of the prescription.

- (6)(a) A PDEA licensed practitioner shall prescribe only FDA-registered dangerous drugs for patient use in any medically-needed and reasonable quantity that is determined by documented clinical need or recommended in the Philippine National Formulary (PNF), Physician Desk Reference, Medical or Veterinary Books or in the usual dosage as set forth in published professional medical or veterinary references. Where the responsible prescribing practitioner has evaluated the patient's condition and determined that there is a need for a longer duration of the therapy, the practitioner may prescribe for a period not to exceed thirty (30) days supply per prescription, except under extraordinary circumstances. The prescribing practitioner shall indicate a specific length of therapy or number of doses in the individual patient's order, as in long-term care, hospice and oncology patients.
  - (b)Prescribing and dispensing of parenteral form of dangerous drugs shall be for administration to patients in PDEA-licensed hospitals and other institutions authorized by the Department of Health as institutional dispensers under their care, or in temporary field hospitals during emergency situation, or in homes where the patient has an attending physician and a nurse.
- (c) A prescription is valid when it is issued for a legitimate medical purpose in the usual course of professional practice by a PDEA-licensed practitioner. A practitioner shall not prescribe, administer, or otherwise provide, or cause to be provided any dangerous drug to a person who the practitioner has never personally physically examined and diagnosed except in institutional settings and on-call situations.
- (d) A PDEA licensed practitioner may prescribe a dangerous drug for patient use for up to thirty (30)-day supply of Philippine Schedules 2, 3, and 4 dangerous drugs per prescription.
  - (i) In extraordinary circumstances, where the prescriber:
    - 1) considers more than thirty (30) days is clinically indicated, the prescribing physician may issue multi-month prescriptions, not exceeding thirty (30) days supply per prescription or a total of ninety (90) days supply for drugs in Schedule IV of the 1971 UN Convention, all dated on the day of issue and with written instructions on the second prescription of when to obtain the medicine. In such cases, the prescriber shall indicate on the face of the prescription, the number of prescriptions issued to the patient i.e. one of 3 Rx, two of 3Rx and three of 3 Rx; and
  - after having made a prescription for thirty (30) days supply and the condition of the patient requires more dose medication than originally assessed, the prescribing physician may issue a supplemental prescription within the thirty day period when the original prescription was made.

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

- (e) A practitioner may prescribed a sixty (60) days supply of Philippine Schedule 4 drugs for the treatment of epilepsy and dystonia.
- (f) Dangerous drugs covered under Philippine Schedule V are to be prescribed as necessary.
- (g) A prescription shall not be issued in order for an individual PDEA-licensed practitioner to obtain controlled substances for the purpose of general dispensing/selling to his/her patient or for his own use.
- (7) Medicines prescribed for an individual patient must be supplied to, and used by that patient only. A medical practitioner must not use patient-specific dangerous drug prescriptions to replace or 'top-up' their bags for home visits even if the stock was used for that patient initially.

- (8) A medical practitioner planning 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 dangerous drug preparation, shall ensure that a patient's medical history has been obtained and a physical examination has been conducted, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of drug abuse, and the nature, frequency, and severity of any pain. The practitioner shall document the diagnosis and the medical need for the prescription in the patient's medical record. The medical record must reflect:
  - (i) a recognized medical indication for the use of the dangerous drugs:
  - (ii) the generic and brand name of the dangerous drugs
  - (iii) the dosage, strength, and quantity of the dangerous drugs;
  - (iv) specific instructions to the patient about frequency of use; and
  - (v) patient response to the treatment.

A practitioner shall remain alert to the possibility that 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.

- (9) (a) A prescription shall not be issued for the dispensing of dangerous drugs and/or drug preparations containing controlled chemicals to a drug-dependent person for the purpose of continuing his dependence upon such drugs.
  - (b) Unless the practitioner is properly registered by the DOH to conduct a treatment program, a practitioner shall not prescribe or administer a dangerous drug if that drug is intended for "detoxification" or "maintenance treatment," except:
    - (i) To relieve acute withdrawal symptoms, provided that:
      - 1) such treatment does not exceed seventy two (72) hours;
      - 2) not more than (one) 1-day's supply of the drug is provided to the patient at a time; and
      - arrangements are made for referring the patient to a drug treatment program for treatment.
    - (ii) As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility."
- (10) (a) In consonance with Section 30(1)(c)(i)(ii), a physician may store in his/her clinic or carry in his medical carry/emergency bag a reasonable quantity of such drugs, including, paraphernalia for administering the drug to a patient. Acquisition of the dangerous drug in reasonable quantities shall be on patient-based-actual-monthly-consumption and mode of resupply, and shall be through an approved local order permit. He/She shall maintain a record of receipts and disposal in a register and submit semi-annual report of transaction to PDEA.
  - (b) An individual PDEA-licensed practitioner that holds stocks of dangerous drugs should keep stock levels to a minimum but to keep enough to meet clinical needs. The stock level held in an emergency bag should also be kept to a minimum as dictated by previous requirements. Only a single strength of each controlled drug shall be kept in the bag. Oral preparations of dangerous drugs should not routinely be carried in the emergency bag. PDEA shall issue guidelines on the

dangerous drug or drug preparations containing the controlled chemical content of the emergency bag.

- (c) A PDEA-licensed practitioner must ensure that all dangerous drugs under his/her control are kept in a locked container which is constructed and maintained to prevent unauthorized access to the drugs and can only be opened by the licensed practitioner.
- (11) Acquisition of dangerous drugs for compassionate reasons:
  - (a) Where a dangerous drug that is:
    - (i) FDA-registered in the Philippines but is not available;
    - (ii) duly registered as a medicine in a source foreign country but not in the Philippines;
    - (iii) needed for treatment by a patient; and
    - (iv) without any available drug substitute,

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

- (b) FDA shall endorse the Compassionate Permit to PDEA which in turn will endorse it to a license importer/distributor of dangerous drugs for necessary importation process.
- (c) The attending PDEA-licensed practitioner will obtain the drug from the distributor through an approved local order permit.
- (d) The patient shall be responsible to the importer/distributor for the cost of importation.
- (e) The PDEA-licensed practitioner shall keep the drug in a secure location as prescribed in Section 31(10)(c) and record the use of the drug in a register as prescribed in Section 37 of this Regulation. He/she shall submit semi-annual report of transaction to the PDEA. In cases when the medication drug is no longer needed by the patient, it shall be immediately surrendered by the practitioner or the patient or a family member of the patient to the PDEA for proper disposition.
- (12)(a) A veterinary practitioner may only prescribe or dispense a dangerous drug for veterinary or
  - (i) after having actually examined the animal, established the therapeutic need, and documented the clinical justification of the need in the veterinary medical record:
  - (ii) in the usual dosage determined by documented clinical need or as set forth in published veterinary references;
  - (b) An animal or herd is considered to be under the veterinary practitioner's care under the following conditions:
    - (i) a valid veterinarian-client-patient relationship exists. The owner or the owner's agent gave the veterinarian responsibility for the health of the animal or herd in question; and
    - (ii) the veterinary practitioner has personal contact with the animal/herd for diagnosis and treatment and assumed responsibility for the diagnosis, treatment and outcome, and the practitioner has a thorough knowledge of the current health and treatment status of the animal or herd.
  - (c) Hospitalized animals may be prescribed dangerous drugs. Dangerous drugs obtained from a secured storage area shall be recorded as well as the patient information (owner's complete name, animal name, identification number) and initials of the person withdrawing the medication. For parenteral medication, the syringe and needle shall be properly discarded after the drug is

- administered. Dangerous drugs cannot be administered from the hospital unless the veterinarian prescribing the drug is physically present.
- (13)(a)(i) A physician, dentist, veterinarian or other practitioners possessing a valid PDEA S-2 license can purchase at most ten (10) booklets of special prescription forms for dangerous drugs at a time from the DOH or its official distribution sites.
  - (ii) Purchase of new special prescription forms for dangerous drugs will be done when a balance of ten (10) unused prescription forms remain.
  - (b) Special Prescription Forms for dangerous drugs issued to a physician, veterinarian, or dentist, possessing a valid PDEA S-2 license are non-transferrable and accountable forms. These shall be for the exclusive use of a physician, veterinarian or dentist to whom such forms are issued and shall be used consecutively.
  - (c) All unused Special Prescription Form for dangerous drugs shall be immediately surrendered to DOH or its official distribution sites under any of the following circumstances:
    - (i) departure for any place outside the Philippines, if the period of stay therein is more than six months;
    - (ii) cessation of, or retirement from, practice;
    - (iii) non-renewal of PDEA S-2 license;
    - (iv) death 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
    - (v) in any case, the DOH or its authorized representatives shall issue an acknowledgment receipt for the surrendered special prescription forms for dangerous drugs.
  - (d) The licensed practitioner shall keep the used prescription booklets in a separate file in such manner as to be readily accessible to inspection by PDEA, for a period of one year.

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

- (1) No person shall issue a requisition for a dangerous drug and/or drug preparations containing a controlled chemical which requires S2, unless the person is:
  - (a) a PDEA-licensed pharmacist in a hospital/institution; or
  - (b) PDEA-licensed medical practitioner in-charge of the ward/unit/pavilion/department in a hospital/institution.
- (2) Only an authorized pharmacist can issue a supply of a dangerous drug and/or drug preparations containing a controlled chemical which requires S2 to ward or clinic at a hospital/institution for the treatment of a patient therein.