Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

April 25, 2011

ADMINISTRATIVE ORDER
No. 2011 - 0004

SUBJECT: Guidelines for the Distribution and Monitoring of Morphine Sulfate Procured by the Department of Health

I. RATIONALE

The Philippine Cancer Society in 2004 revealed that the Philippines has an estimate of 73,944 new cancer cases annually. The top ten cancer sites are lung (23%); breast (19%); colon and rectum (12%); liver (10%); uterine cervix(10%); prostate(6%); blood (leukemia 6%); stomach(5%); thyroid(5%) and ovary (4%). In the Philippines, the relief and management of cancer pain and palliative care are benchmarked on the World Health Organization's Three-Step Ladder of Cancer Pain Management and the dispensing of _ morphine to Filipino cancer patients has been in existence for years through the Philippine Cancer Pain Control Program of this Department. According to the Pain Society of the Philippines an estimated 50% of patients with cancer requiring pain management remains under-treated due to high cost, poor access to narcotic pain medications, lack of knowledge/acceptance of the program by prescribing professionals, restrictive laws, regulations, policies and “opiophobia" - failure to administer legitimate opioid analgesic because of a fear of the power of these drugs to produce addiction. The World Health Organization reported that the Philippines has an estimated need of 5.3 mg/capita, but has an actual consumption of only 0.23, and has only been able to cover 4.4% of the estimated analgesic (opioid) requirement in the country in 2005. The International Narcotics Control Board (INCB, 2008) reported that the morphine requirement of the Philippines for pain and palliative care amounts to 30 kg but the country was able to procure 5-6 kg only.

lnthe late 1980's, the DOH. through the Philippine Cancer Control Program, procured eight million pesos (P 8M) worth of morphine annually for the indigent cancer (both adult and pediatric) cases. Hospice facilities were the major distribution sites. The annual subsidy for the procurement of morphine in the course of time gradually decreased until the Department of Health stopped the purchase and distribUtion of such pain medications for indigent cases. The use of morphine in pain management and palliative care however, needs to be pursued. Cognizant of this and in an effort to reverse the situation, the Department of Health in 2008 initiated the procurement of P1 1M worth of morphine sulfate for distribution nationwide. Around 500,000 of the 10mg tablets, and 121,250 of the 30 mg morphine sulfate tablets, will be distributed at no cost to indigent cancer patients with moderate to severe pain.

II. STATEMENT OF POLICY

a. All indigent patients, whether out-patient or in—patient, requiring palliative medications, suffering from moderate to severe pain due to cancer, HIV and other diseases, shall receive pain medications (morphine sulfate) at no expense to them, upon presentation of the DOH Prescription Forms indicating the quantity and dosage requirement. Such patients shall include those in the DSWD list under the National Household Targeting System, those with PhilHealth cards indicating Sponsored Program Members and those outside of the above but evaluated by the hospital and or hospice care resident Social Worker.

b. Hospitals shall only allocate a maximum of 20% of the existing stocks of morphine to non-indigent patients but without prejudice to indigent client needs and while supplies are available.

c. Hospice facilities can also refer patients for pain management to distributing hospitals who shall provide the drug upon presentation of the DOH Prescription Form.

d. Morphine sulfate medications shall be distributed by all DOH hospitals, participating Local Government Hospitals, private hospitals and hospice facilities.

e. Services which are not medically necessary, such as cosmetic surgery and other non- palliative interventions shall not be eligible to receive free morphine sulfate.

f. Consistent with the National Insurance Act of 1995 and the Health Sector "Reform Agenda. all Filipinos shall be encouraged to become members of the Philippine Health insurance (PhilHealth) or at least be a dependent of an active member.

III. OBJECTIVE

To provide guidelines for the distribution and monitoring of Morphine Sulfate towards the enhancement of the quality of life by decreasing the under-treatment of patients with severe pain and by improving the accessibility of opiate analgesics.

IV. SCOPE

This guideline covers all DOH hospitals, selected government and private hospitals, selected hospice and morphine sulfate distribution centers nationwide (see attached list).

V. DEFINITION OF TERMS

a. “Dispense" is any act of giving away, selling or distributing medicine or any. dangerous drug with or withOut the use of prescription.

b. “BBB" is the Dangerous Drugs Board, which is the main policy making body on Dangerous Drug Prevention and Control.

c. “DSWD" is the Department of Social Welfare and Development, which is the national agency mandated to identify the poor households.

d. “DOH-Prescribed Prescription Form" is the “yellow" prescription form for dangerous drugs that is made of a special kind of paper exclusively issued by and. obtainable from DOH.

e. “Hospices" are facilities which specialize on the type of care, and a philosophy of care which focuses on the palliation of a terminally ill patient's symptoms. These symptoms can be physical, emotional, spiritual or social in nature. Hospice facilities under this guideline should seek accreditation by the National Hospice and Palliative Care Council of the Philippines (Hospice Philippines). Furthermore, they should enter into an agreement with the DOH regarding the utilization of morphine.

f. “License" is a written permission or authorization.

g. “MMD" is the Materials Management Division, an office under the Department of Health charged to supervise / manage logistics and supplies.

h. “Morphine" is a highly potent opiate analgesic drug, is the principal active agent in opium, and is considered to be a prototypical opioid. '

i. “NCDPC" is the National Center for Disease Prevention and Control Center, an office under the Department of Health which oversees the Non—communicable Disease Program.

j. “OSC" is the Office for Special Concerns, an office under the Department of Health which handles the Dangerous Drug Abuse Prevention and Treatment Program.

k. “PDEA" is the Philippine Drug Enforcement Agency; the office charged as the implementing arm of the DDB and as such is responsible for the efficient and effective law enforcement of all the provisions on any dangerous drug and/or controlled precursor and essential chemical as provided under RA 9165.

l. “Prescription" is a written direction by a practitioner that a stated amount of a dangerous drug or drug containing Table I Controlled Chemical, be dispensed for the person named therein.

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

n. “S2 License" is the license required to authorize physicians, dentists and veterinarians to

prescribe (a) dangerous drugs preparation; and/or (b) drug preparations, in parenteral or tablet or capsule form containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient.

o. “S3 License" is the license required to sell, procure, acquire, deal in or with specified (a) dangerous drugs preparations or (b) drug preparations, in parenteral or tablet or capsule form, containing Table 1 controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient.

p. “S4 License" is the license required to sell, procure, acquire, deal in or with specified (a) dangerous drugs and their preparations, (b) drug preparations, in parenteral or tablet or capsule form, containing Table 1 controlled chemicals for wholesale distribution to license holders, and (c) Table I controlled chemicals used in the manufacture of drugs. The license holder need not obtain another license of the same nature of activity for such controlled chemicals.

q. “Table I Controlled Chemical" means chemicals enumerated. in the list of substances in Table II of the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which is an integral part of the Republic Act 9165 otherwise known as the “Comprehensive Dangerous Drugs Act of 2002".

r. “Wholesale distribution," means activities by any person, which stands between the manufacturer and the retail seller in purchases, consignments, or contracts for sale of dangerous drugs or controlled chemical and their preparations.

VI. GENERAL GUIDE LINES

The following shall be observed in the management and distribution of opiate analgesic (Morphine sulfate):

a. The DOH Central Bids and Awards Committee shall be responsible for finalizing the general specifications and packaging of the drug pursuant to the procurement plan.

b. The National Center for Disease Prevention and Control of the DOH shall be responsible for technical specifications and the quantities, allocation of the drug as well as funding of the procurement of Morphine sulfate preparations starting 2011.

c. The Office for Special Concerns through the Dangerous Drugs Abuse Prevention and Treatment Program (DDAPTP) shall monitor the distribution and allocation of drug and related logistics.

d. The DOH-Material Management Division (MMD) shall be responsible for coordinating with the Philippine Drug Enforcement Agency (PDEA) in securing the necessary permits for the purpose of purchase and distribution of the drug.

e. Stocks shall be secured by the MMD and shall be allocated depending on the need of a particular region or location as set/identified. by the NCDPC.

f. Distribution and dispensing units shall comply with the regulatory requirements as provided for under Dangerous Drugs Board (DDB) Regulation No. 3 s. 2003 or the “Comprehensive Guidelines on importation, distribution, manufacture, prescription, dispensing and sale of, and other lawful acts in connection with dangerous drugs, controlled precursors and essential chemicals and other similar or analogous substances" (downloadable at www.pdea.gov.ph):

1) Hospitals and. hospices shall secure from the PDEA the appropriate licenses for wholesale distribution (S-4 license) and retail dispensing (S-3) whichever is applicable;

2) Local stock transfer from one license holder to another or from one activity to another shall be covered by an approved PDEA Form 1—04 (LOCAL TRANSFER PERMIT);

3) Dispensing by a current PDEA registered outlet shall require a properly filled out DOH prescribed prescription form issued by a current PDEA S—2 License holder.

g. Dispensing sites are / shall be informed on the initial shipment of stocks and succeeding shipments thereafter.

1) Initial shipment volume shall be determined at the level of the DOH-Central Office by the OSC as indicated by the allocation list provided by NCDPC.

2) Succeeding shipments shall be on a need basis while supplies are available.

a) Hospitals shall be required. to inform the OSC, DOH when the available stock reaches the critical volume of thirty percent (30%) of the initial allocation for immediate replenishment;

b) Likewise, hospitals shall also report to the OSC the average monthly consumption and available stock volume, ten (10) months before the expiration date and, as required by the DOH-Central Office;

c) Hospitals may also submit requests to the OSC for increased allocation using the following basis:

i. anticipated increase in the number of patients;

ii. increased prescribing due to training, residency, or the addition of qualified doctors with pain management patients;

iii. emergency needs such as the large amount dosages needed for the cancer patient to achieve adequate pain control.

h. Only a DOH Accredited Freight Forwarder shall be authorized to transport the medications/supplies. The following are the transport and receiving procedures:

1) Duplicate copy of the approved PDEA permit and respective hospital purchase request shall accompany the shipment and shall form part of the transport documents;

2) The transported medication should be properly insured,

3) Inter-island. transport shall be by airfreight,

4) Supplies shall be received by the designated Supply Officer and/with the Chief Pharmacist following recording and reporting procedures as provided for by DDB Regulation No 3, 2003.

i. Each hospital shall strictly comply with the regulatory control measures set forth by PDEA to include among others the prescribed security for storage, dispensing, distribution, recording and reporting requirements.

j. The hospitals/hospices shall dispense the medications free of charge to indigent patients with moderate to severe pain. Participating hospices, in consonance with Presidential Proclamation No. 1 l 10 ofthe President of the Republic of the Philippines dated July 25, 2006, shall seek accreditation by the National Hospice and Palliative Care Council of the Philippines (Hospici Philippines). Morphine distribution shall comply with the following: 1:er

1) Morphine dispensing shall be covered by a duly accomplished DOH prescription issued by a current PDEA S2 licensed doctor and ilentist. The prescription shall be presented to the Hospital pharmacy;

2) Patients or their families shall submit an accomplished “Statement of Commitment" to return any “unused" medications when instances arise that the patient would no longer need the Morphine. The Morphine shall be returned to the same dispensing hospital pharmacy following existing prescribed reporting system;

3) The patient, family, guardian or person duly authorized in behalf of the patient should ensure the security of Morphine against loss, theft or misuse/abuse;

4) Reporting and recording of dispensed medication shall follow DDB Regulation No 3, 2003 using the same required register, forms and attachments and;

5) During the transition when hospices are seeking accreditation of Hospice Philippines, hospices can refer clients with morphine prescription to distributing hospitals following the above—mentioned procedures (refer to 8a), pending their accreditation. This 15 to ensure smooth delivery of services to clients in need of pain management.

k. The MMD-DOH, upon approval by NCDPC shall distribute medications to non-DOH hospitals and hospice/palliative units upon presentation and receipt of a request letter from the concerned service provider. A Memorandum Of Agreement (MOA) between the Department of Health and a non-DOH government hospital or a hospice facility shall be undertaken. The said facility shall be responsible in securing approval of the PDEA Transport permit.

l. Hospitals who wish to distribute to authorized hospice/palliative care and other service units shallibe required to secure a PDEA—S4 License (for the wholesale distribution).

m. Hospice/ palliative care and other service units shall be required to secure a PDEA-S3 License to authorize them to dispense directly to patients and shall follow all of the above—mentioned procedures in-compliance to DDB Regulation No 3, 2003.

1) S4 and S3 application forms can be downloaded at the PDEA website: www. pdea. gov. ph
2) Applications by government hospitals/facilities are free of charge.

n. The DOH, PDEA, DDB and other authorized agencies may conduct inspection and monitoring visits to ensure compliance to this Order.

VII. ROLES AND RESPONSIBILITIES

a. National Center for Disease Prevention and Control (NCDPC):

1) Shall include funds for the procurement of pain management medications in its operational plan, work and financial plan and procurement plan from hereon;

2) Shall provide technical assistance in determining types and quantity of medications to be procured, taking into consideration the dosage requirements and the “step — ladder" approach;

3) Shall determine the quantity / allocation of the medications per hospital / region;

4) Shall participate in technical working group discussion;

5) Shall monitor movement of said logistic and its utilization and;

6) Shall provide input on the messages to be developed on pain management.

b. Central Office Bids and Awards Committee (COBAC):

1) Shall be responsible in advertising and / or posting of bidding documents to interested bidders;

2) Shall facilitate the procurement process from eligibility screening, evaluation of bids, awarding of contract and post qualifications and;

3) Shall monitor the procurement activities for proper reporting to relevant agencies when required.

c. Materials Management Division (MMD) —Administrative Service:

1) Shall coordinate with PDEA for the issuance of necessary permits for the transfer, transportation and distribution of Morphine Sulfate tablets;

a) The PDEA Local Purchase Form will be prepared by the Pharmacist with valid S4 license before procurement for approval at the Compliance Service of the PDEA.

b) The approved Local Purchase Form will be submitted to the Procurement Division for processing of the procurement.

c) The supplier will notify schedule of delivery to the MMD —- DOH Quirino Warehouse and the items will be received together with other documents in accordance to the quantity and specification stated in the Purchase Order.

d) DOH Hospitals with valid PDEA S3 License can request for the Morphine Sulfate by sending their PDEA Local Purchase Form and a copy of their valid S3 License to the MMD — DOH Quirino Warehouse. The Pharmacist will coordinate with the Compliance Service of PDEA for approval of the transaction.

e) The copy of the approved Local Purchase Form, Invoice Receipt and Bill of Lading will be prepared together with the stocks of Morphine Sulfate requested by the DOH Hospital.

f) F01 the transportation of Morphine Sulfate tablets, the DOH contracted forwarder will be assigned for the distribution to the DOH Hospitals.

g) The original copy of the Local Purchase Form will be filed by the Pharmacist and the transaction recorded in the Dangerous DrugBook needed for the semi— annual reporting to the PDEA.

2) Shall take charge of the security of the inventory;

a) Morphine Sulfate tablets are placed in a secure storage room at the MMD - DOH Quirino Warehouse upon receipt from the supplier and inspection by the DOH inspection team and FDA inspectors for FDA test analysis sampling.

b) Storage place and premises are in fit condition, appropriate temperature and has sufficient space.

c) Adequate supervision should be properly carried out at all times by the Pharmacist and Supply Officer who have access in handling Morphine Sulfate tablets.

d) Report of monthly inventory of stocks will be submitted to the OSC - DDAPTP prepared by the

Pharmacist and verified by the Officer-In—Charge of MMD.

3) Shall assist in the monitoring of logistics distribution and drug utilization;

a) Coordination with the DOH Hospital Pharmacist regarding the sending of their Local Purchase Form for approval at the Compliance Service of PDEA.

b) Verification of the proper distribution of Morphine Sulfate tablets and documents to the DOH Hospitals.

c) Assists in the information dissemination regarding the availability of Morphine Sulfate tablets at the DOH Central Office Warehouse.

d) Assists in the monitoring of the utilization of Morphine Sulfate tablets by the DOH Hospitals.

d. Dangerous Drug Abuse Prevention and Treatment Program - Office for Special Concerns (DDAPTP-OSC):

1) Shall assist in the formulation of related policies for approval of the Dangerous Drugs Board; -

2) Shall convene the technical working group to- discuss among others the availability and accessibility of opioid analgesic for pain and palliative care;

3) Shall determine the volume of shipment for distribution to sites based on the allocation as initially submitted. to NCDPC and the subsequent requests of the respective sites as approved by NCDPC and;

4) Shall assist in the monitoring of logistic distribution and drug utilization.

e. National Center for Health Promotions (NCHP):

1) Shall assist in the dissemination on information pertaining to pain management;

2) Shall develop necessary Information Education and Communication materials on pain management and morphine sulfate use and;

3) Shall help mobilize support groups for easy access and utilization of the pain management medications.

f. Information Management Service (IMS):

1) Shall assist in the development of an IT—based reporting system of pain medication utilization which shall be housed under the Department of Health website and;

2) Shall help capacitate hospitals, hospices and other partners in the use of the IT reporting system.

g. Centers for Health Development (CHDs):

1) Shall assist in the monitoring of pain management medication distribution and utilization;

2) Shall help identify and mobilize support groups and organizations that can facilitate easy access and utilization of the pain management medications and;

3) Shall provide feedback to the NCDPC and the DDAPTP of the necessary arrangement that will help improve distribution and utilization systems.

h. Hospitals:

1) Shall ensure the security of the pain medications which should follow the PDEA set standards;

2) Shall be responsible in securing all the necessary permits for the transportation, utilization and dispensing of the pain medications;

3) Shall determine eligibility of recipient to receive pain medications and;

4) Shall submit regular utilization reports to the NCDPC, DDAPTP and CHDs.

VIII. SEPARABILITY CLAUSE

In the event that any provision of this guideline is declared invalid for any reason, the other provisions shall remain in effect.

IX. EFFECTIVITY

This guideline shall take effect after fifteen (15) days after publication in the official gazette or in a newspaper of general circulation.

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