Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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ADMINISTRATIVE ORDER
2021 - 0038

SUBJECT: Framework for the Philippine Essential Medical Devices List and Price Reference Index

I. BACKGROUND / RATIONALE

The World Health Organization (WHO) defines medical devices as articles, instruments, apparatuses or machines that are used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Medical devices play an important role in the delivery of health care services, and it is crucial to ensure their quality, safety, availability, accessibility, and affordability.

Section 28 of the Republic Act 11223, or otherwise known as the *Universal Health Care Act* provides the government the mandate to institute strategies that will ensure the availability, accessibility, and affordability of medical devices such as the following: developing price reference indices for medical devices; ensuring consumers' choice through price transparency; central price negotiation; and regulation of mark-ups particularly in government hospitals. In addition, the selection and management of health technologies for public funding is emphasized in the UHC Act in *Section 34* on *"Health Technology Assessment"* or HTA.

Due to the COVID-19 situation, the Office of the President (OP) through a Memorandum to the DOH dated February 4, 2020 exempted and classified selected medical devices as basic necessities, thus subjecting these products to the imposition of price ceilings.

In response to this, the DOH constituted the Medical Device Unit (MDU) under the Health Regulation Team (HRT) – Pharmaceutical Division (PD) through Department Personnel Order No. 2020-1837 and its amendment to support the government in addressing the current need of strengthening the medical device and personal protective equipment (PPE) supply chain, and its monitoring and price regulation in the country.

II. OBJECTIVES

This Order aims to set the national framework for developing the Philippine Essential Medical Device List (PEMDL) and Price Reference Index for Medical Devices and supplies in the DOH Offices/Bureaus, Centers for Health Development (CHDs) and all healthcare facilities under the DOH procuring and/or utilizing medical devices, supplies and equipment herein referred to as End-User.

The following are its specific objectives:

A. To establish a standard system and methods for creating and maintaining a database of essential medical devices;
B. To set the price reference index for medical device as the recommended prices for all DOH health facilities; and
C. To provide guidelines on the enforcement, implementation, and monitoring of the price reference index system across DOH End-User Units.

III. SCOPE

This Order shall be applicable to all the end-users such as the health care facilities and their practitioners under the DOH, its offices/units, retained and corporate hospitals, treatment and rehabilitation centers, Centers for Health Development, and the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM), pursuant to the RA No. 11054 or the "Organic Law for BARMM".

IV. DEFINITION OF TERMS

A. **Distributor** - refers to either a **distributor/importer/exporter or distributor/wholesaler:**
   a. **distributor/importer/exporter refers to** any medical device establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets

   b. **distributor/wholesaler** refers to any medical device establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on a wholesale basis.

B. **End-User** – refers to all DOH Offices/Bureaus, Centers for Development (CHDs) and all healthcare facilities under the DOH procuring and/or utilizing medical devices, supplies and equipment.

C. **External Reference Pricing** – refers to the practice of using the price of medical devices and supplies in one or several jurisdictions to derive a benchmark or reference price.

D. **Internal Reference Pricing** – refers to the practice of pricing medical devices based on calculations of manufacturers' prices (e.g. latent class analysis/LCA, mean, median, etc.) of medical devices and supplies that are therapeutically comparable and interchangeable, to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement rate of a product.

E. **Landed Cost** – includes the price of goods, shipment costs, insurance fees, custom fees, and other costs incurred along the way.

F. **Manufacturer** – refers to any medical device establishment engaged in any and all operations involved in the production of a medical device including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.

G. **Mark-up** - refers to the amount added to a cost price in calculating a selling price, especially an amount that takes into account overhead and profit.

H. **Medical Devices** – refers to any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

- intended by the manufacturer/product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease, investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information for medical or diagnostic purposes by means, of in vitro examination of specimens derived from the human body.

I. **Medical Device Quality Management System (MDQMS)** – refers to a structured system of procedures and processes covering all aspects of design, manufacturing, supplier management, risk management, complaint handling, clinical data, storage, distribution, and product handling of medical devices.

J. **Medical Devices and Supplies Price Reference Index (MDSPRI)** - refers to the mandated ceiling price of essential medical devices for government bidding and procurement set by the DOH for all DOH facilities in order to have a transparent and unified pricing scheme in medical device procurement. Winning bid prices for medical devices shall therefore not exceed the Price Reference Index.

K. **Philippine Essential Medical Device List (PEMDL)** – refers to the list of medical devices considered as important or necessary for preventive, diagnostic, therapeutic, or rehabilitative procedures carried out in government health facilities.

L. **Specialty Hospital** - refers to a hospital which provides services for one particular illness or disease or health medical care need, with the highest medical care rendered by medical experts using highly specialized equipment for a specific medical problem.

M. **Technical Specifications** – refers to the functional and performance requirements of a product.

N. **Transport Margins** - consists of those **transport** charges paid separately by the purchaser in taking delivery of the goods at the required time and place.

V. GENERAL GUIDELINES

A. The Philippine Essential Medical Device List (PEMDL) is hereby created to guide in the procurement of medical devices and to promote price transparency in the Philippines. The PEMDL shall set the priority medical device list with technical specifications and corresponding price reference index for procurement to reduce the variations in the prices of medical devices in the public sector.

B. The PEMDL's technical specifications shall be guided by the recommendation of the Health Technology Assessment Council (HTAC) in recommending innovative medical

devices for public funds and an Expert Advisory Committee to create and update the Essential Medical Device List in accordance with HTAC recommendation.

C. The Medical Device Unit (MDU) shall compute, manage, and maintain the Medical Devices and Supplies Price Reference Index (MDSPRI) that shall include all medical devices and supplies listed in the PEMDL.

D. The first edition of the PEMDL shall be developed based on the World Health Organization's (WHO) technical specifications for medical devices as stated in the Department Memorandum 2019-0037, entitled "Interim Guidelines on the Development of Technical Specifications for Medical Devices and Equipment without Radiologic Function" and from the latest purchase orders of the End-User Units. The updating shall be done in coordination with HTAC.

E. New medical devices being considered for inclusion in the PEMDL are required to undergo Health Technology Assessment. The entire HTA process shall adhere to the established guidelines and shall be under the jurisdiction of the HTAC.

F. Through the power of the Health Secretary, the MDSPRI shall be the maximum procurement price of essential medical devices across all DOH health facilities, Offices/Bureaus, and CHDs.

G. Only the medical devices included in the PEMDL shall be procured by DOH health facilities, Offices/Bureaus, and CHDs. As stated in the Section V under General Guidelines of the Department Order 2020-0259 entitled, "Guidelines for the Implementation of Medical Devices and Supplies and Consignment System (MDSCS)", the Price Reference Index for Medical Devices shall serve as the basis for the pricing of devices and supplies that are included in the Consignment Agreement. It shall also be the basis for mark-ups and consignment fees.

H. The MDSPRI shall be calculated every year based on prevailing procurement prices of medical devices in government health facilities using the data collected by the Medical Device Unit from the CHDs, DOH Retained Hospitals, Central Office Bids and Awards Committee (COBAC), Procurement Service of the Department of Budget and Management (PS-DBM), and the DOH health facilities and End-User Units.

I. The PEMDL manual and its detailed content will be available through an issued Manual of Operation. The said MOP shall be available at the DOH and PD website (www.doh.gov.ph; www.pharma.gov.ph).

J. The PEMDL and MDSPRI shall be reviewed and updated annually by the MDU and shall be made public by the DOH through web-based posting, and distribution of booklets to all government health facilities.

VI. SPECIFIC GUIDELINES

A. Contents of the PEMDL Manual

1. The PEMDL Manual shall include the list of Priority Medical Devices and Supplies together with corresponding technical specifications.

2. The technical specifications (TS) of the medical device shall be such as, but not limited to the following: a) Generic Name; b) Name, Code, Category (based on

Global Medical Device Nomenclature/GMDN or Universal Medical Device Nomenclature System/UMDNS); c) Area of Use; and d) Product Specification.

3. Medical devices and supplies withdrawn from the Philippine market due to safety reasons shall be deemed delisted from the PEMDL effective on the date of the order for withdrawal by the FDA.

B. Medical Devices and Supplies Price Reference Index (MDSPRI)

1. All CHDs, DOH Retained and Specialty Hospitals, MOH-BARMM, DOH Procurement Service and Philippine Pharma Procurement Inc. (PPI) must submit a copy of their Annual Purchase Orders (PO) and list of procured medical devices and supplies to the DOH-PD through the MDU. The data to be submitted shall include the following: name, unit, description with specification/s, quantity, unit cost, total cost, mode of procurement, name of supplier, additional costs (warranty, services such as training and maintenance).

2. All Purchase Orders (PO) and list of procured medical devices from the previous year shall be submitted to the DOH-PD through the MDU on or before the end of first quarter of the succeeding year.

3. For procurement documents coming from PS-DBM, the MDU shall formally request the same to PS-DBM once every quarter. The MDU shall consolidate, process, analyze and synthesize the price data coming from the end-users and PS-DBM and generate a price report to be disseminated every third quarter of the year through the DOH and PD website on Medical Devices and Supplies Price Reference Index (www.doh.gov.ph; www.pharma.gov.ph).

4. The MDSPRI shall be calculated from the lowest to the median of winning bid prices of medical devices sourced from manufacturers and local distributors licensed by the Food and Drug Administration.

5. The MDSPRI shall reflect the final acquisition cost to the end-users which should include the landed cost, packaging, delivery, installation, training, warranty, maintenance or quality assurance, manufacturing overheads, and regulatory/FDA fees. The MDSPRI shall exclude other costs such as hospital/facility services, storage fees, and other reasonable mark-ups to be determined by the DOH.

6. For geographically isolated and disadvantaged areas (GIDAs) and island provinces, transport margins shall be considered in calculating the price reference index for medical devices.

7. In general, MDSPRI for each essential medical device shall be set at the median of the range of prices collected from the manufacturers, distributors, and suppliers. Where participation in government tenders is only limited to two (2) suppliers only for a particular medical device, the MDSPRI shall be derived from the lowest bid price collected;

8. For innovative, proprietary, patented and single-sourced medical devices, the lowest and most advantageous centrally negotiated procurement price by the Price Negotiation Board (PNB) shall be considered in accordance with

RA No. 9184 or the Government Procurement Reform Act and other Government Procurement Policy Board (GPPB) issuances. Pooled procurement may also be used to obtain lower procurement price most especially for high cost medical devices;

9. In situations where there is difficulty in achieving the mandated price ceiling, the DOH shall develop an alternative procurement mechanism such as importation as provided for by law, and shall be accessible to all national and local government procuring entities; and

10. PhilHealth shall consider the MDSPRI when costing and developing their benefit packages in accordance with *UHC Act, Section 28 Affordability, 28.7.*

11. The DOH-MDU shall update the price reference index at least every year and make them public through various platform, including web based databases, price booklets, and publication in major newspapers.

C. Expert Advisory Committee

1. An "Expert Advisory Committee" shall be convened to assist the MDU in the development of the Philippine Essential Medical Device List to be chaired by the Undersecretary of the Health Regulation Team or his/her duly designated representative.

2. Composition:

   a. The Expert Advisory Committee shall be composed of experts from the following fields; Biomedical Engineering, Medical Technology, Radiology, General Surgery, Orthopedic, OB-GYN, and Primary Care. The members of the committee may seek and call assistance from other experts of professional societies if deemed necessary.

3. Qualifications:

   a. Of good moral character and with high level of integrity;
   b. Known expert in the field; and
   c. Willing to disclose perceived and actual conflicts of interest which can influence and/or compromise their recommendations to the DOH.

4. Specific Functions:

   a. Provide technical specifications of medical devices listed in the PEMDL;
   b. Assist the MDU in the development of guidelines for the conduct of market studies of end-users; and
   c. Conduct market study for specific medical devices as needed or as requested by the Office of the Secretary (e.g. big ticket item/high-priced medical device).
   d. The MDU shall be the Secretariat of the Expert Advisory Committee.

VII. ROLES AND RESPONSIBILITIES

A. The **DOH - Health Regulations Team** shall

1. Provide oversight function to the MDU and the Technical Working Groups that will be created to assist in the development of the PEMDL;

2. Issue relevant orders to support the operations of the MDU.

The **Medical Device Unit** shall

1. Set policies, procedures, and develop new guidelines related to the development and maintenance of PEMDL and MDSPRI (e.g. electronic price monitoring for medical devices);

2. Oversee and manage the over-all implementation of PEMDL and PRI for Medical Devices;

3. Develop tools to monitor the adherence of all end-users covered by this Order;

4. Provide technical assistance to end-users for the implementation of this program and help them address issues and concerns encountered;

5. Conduct a regular assessment of the PEMDL together with all the stakeholders in public health facilities, other government agencies, health providers, patients and the industry; and,

6. Monitor the compliance of all end-users to the set guidelines for the MDSPRI and submit it to the DOH.

B. The **Food and Drug Administration** shall

1. Provide technical input and essential data requirement in the development of the Philippine Essential Medical Devices List and Price Reference Index for Medical Devices;

2. Set the minimum standards of safety, efficacy, and quality of medical devices;

3. Provide technical assistance in the development of new guidelines with regards to the PEMDL and Price Reference Index for Medical Devices;

4. Provide updated list of licensed manufacturers (local and international) and distributors of medical devices through their official website.

C. The **Price Negotiation Board** shall

1. Determine which medical devices are to be included in the negotiations;

2. Collect and analyze data on external reference pricing, prevailing market prices (local and international), as well as volume of medical devices to be negotiated; and,

3. Negotiate prices of selected essential medical devices for the entire public sector.

D. The **Health Technology Assessment Council** shall

1. Assess medical devices based on the HTA decision framework; and,

2. Provide recommendation on the funding coverage of the medical device by DOH and PhilHealth.

E. The **CHDs, DOH Retained and Specialty Hospitals, MOH-BARMM, DOH Procurement Office and PPI as the End-users** shall

1. Adhere to the Medical Devices and Supplies Price Reference Index set by the DOH;

2. Regularly submit the medical device procurement data and other relevant documents to the MDU through actual Purchase Orders and standard forms prescribed by the DOH;

3. Ensure the fair and efficient pricing of medical devices through good governance and proper implementation of the DOH's strategies to make medical devices affordable, accessible and safe;

4. Attend consultative meetings and participate actively in the decision-making processes related to the development of "Philippine Essential Medical Devices List" and "Medical Devices and Supplies Price Reference Index".

VIII. SEPARABILITY CLAUSE

If any provision in this Administrative Order, or application of such provision to any circumstance, is held invalid, the remainder of these Guidelines shall not be affected thereby.

IX. EFFECTIVITY

This Administrative Order shall take effect within fifteen (15) days after its publication in a newspaper of general circulation and upon filing with the University of the Philippines Law Center of three (3) certified copies of this Order.

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Secretary of Health