Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

28 November 2022

DEPARTMENT MEMORANDUM
No. 2022 - 0545

TO : **DIRECTORS OF CENTERS FOR HEALTH DEVELOPMENT (CHDs), CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA, EXECUTIVE DIRECTORS OF SPECIALTY HOSPITALS, MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (MOH- BARMM) AND OTHERS CONCERNED, HEALTH FACILITIES ENHANCEMENT PROGRAM (HFEP) - FOR DISSEMINATION TO ALL DOH HOSPITALS**

SUBJECT : **Interim Guidelines on the Process and Methods for the Selection of Medical Devices for Inclusion in the Philippine Essential Medical Device List (PEMDL)**

The Republic Act 11223 or the *Universal Healthcare Act* Implementing Rules and Regulations mandates the Department of Health to develop price reference indices before mark ups for medical devices and supplies. The law mandates that all DOH-owned health care facilities shall procure medical devices and supplies guided by the price reference index for medical devices. As part of the development of the price reference index for medical devices and supplies, a list of essential medical devices procured by DOH health facilities is necessary to identify the medical devices to be included in the price reference index. As such, the Administrative Order No. 2021-0038 titled *Framework for the Philippine Essential Medical Devices List and Price Reference Index* and Department Memorandum 2019-0337 titled *Interim Guidelines on the Development of Technical Specifications for Medical Devices and Equipment Without Radiologic Function*, was created.

In accordance with AO 2021-0038, the Department of Health, through the Pharmaceutical Division - Medical Device Unit (PD-MDU) and the Health Technology Assessment Division (HTAD), has been developing the **Philippine Essential Medical Devices List (PEMDL)** which aims to assist and guide all DOH health facilities to efficiently source quality and affordable medical devices and supplies in the public sector through the **Medical Devices and Supplies Price Reference Index (MDSPRI)**.

An Expert Advisory Committee (EAC) supported by staff from the PD-MDU was created under the Pool of Experts of the Health Technology Assessment Council (HTAC) which is supported by staff from the HTAD based on Department Personnel Order No. 2021-2780-A with the subject *Amendment to the Department Personnel Order No. 2021-2780 entitled "Creation of the pool of clinical experts for consultation on the evaluation of assessment topics" to include Expert Advisory Committee as additional experts* to assist in the assessment of essential medical devices and supplies to be included in the PEMDL.

The PEMDL (Initial list) consists of medical devices that were routinely procured by DOH hospitals and DOH programs, are currently part of PhilHealth benefit packages, and currently required for licensing of health facilities. To facilitate the process of inclusion of medical devices that are essential in the operations of health facilities and relevant Offices of the DOH, the EAC and HTAC jointly developed a flowchart (*Annex A*) for the screening of medical devices proposed to be included in the PEMDL to fulfill the stipulations of the AO 2021-0038.

I. General Guidelines

A. The PEMDL shall serve as guidance for all DOH health facilities to efficiently source quality and affordable medical devices and supplies until such time when the PEMDL has covered all medical devices necessary for the majority of conditions being addressed by government hospitals.

B. The Medical Device Unit as stipulated in AO 2021-0038 shall annually collect procurement data of medical devices and supplies from all 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-users). The End-users shall comply with the submission of purchase orders of medical devices and supplies every year for the purpose of identifying procured medical devices for its inclusion in the PEMDL and its prices for the setting of MDSPRI.

C. The proposed medical devices for inclusion in the PEMDL shall be screened using the flowchart by the MDU and EAC, to be validated by the HTAD and HTAC. A medical device that has passed the screening may be recommended by the HTAC to be directly included in the PEMDL or to undergo additional analysis by the HTAC.

D. The PEMDL that will be issued together with this issuance will be an initial list that shall be updated regularly.

E. End-users (i.e., All DOH Offices/Bureaus, Centers for Health Development and all healthcare facilities under the DOH procuring and/or utilizing medical devices, supplies and equipment) may procure medical devices that are deemed important for continuous clinical/medical operations of their health facilities until December 2025 when the PEMDL would have covered all medical devices necessary for the majority of the conditions being addressed by government hospitals. By then, end-users are required to adhere to the list of medical devices for public procurement in accordance with the latest version of the PEMDL.

F. To ensure the safety and quality of medical devices being procured by the DOH and its attached hospitals, all are required to purchase only medical devices that have the appropriate certification issued by the Philippine Food and Drug Administration. Refer to these links for the list of authorizations by the Philippine FDA on medical devices: Certificate of Product Registration and Certificate of Medical Device Notification.

II. Process and Methods of Selection of Devices for Inclusion in the PEMDL

A. For PEMDL (Initial list), the starting pool of essential medical devices emanated from the following:
   1. Annual collection of procurement data from end-users which 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. List of medical devices that are already covered by existing Philhealth benefit packages and DOH programs as part of standard of care
   3. List of medical devices required for licensing of health facilities by the Health Facilities and Services Regulatory Bureau (HFSRB)

B. To ensure the safety, quality, and conformance with regulations, medical devices shall be validated through the FDA verification portal or submission of regulatory documents to check that the appropriate certification/s based on its risk classification has been issued for the medical device.

C. Medical devices that are not registered with the FDA shall not be included in the PEMDL. Suppliers, distributors and retailers of such products shall be advised to secure the required applicable certification from the FDA to proceed with the assessment.

D. Medical devices shall then be assessed by the MDU and EAC as being part of standard of care and deemed as truly essential in any healthcare setting based on the following documents and guidelines:
   1. List of essential medical devices included in the World Health Organization (WHO) Medical Device Technical Series (MDTS) and other relevant WHO technical documents adopted by the DOH (*Annex B*).
   2. Clinical practice guidelines crafted and/or adopted by the Disease Prevention and Control Bureau (DPCB) as the National Clinical Practice Guidelines (NCPG) Clearing House (*Annex C*) in consultation with relevant experts and professional medical societies.
   3. List of medical devices required for licensing of health facilities by the Health Facilities and Services Regulatory Bureau (HFSRB).
   4. Validation with clinical experts on whether a medical device is standard of care for a medical condition

E. A medical device that has passed the screening may be referred by HTAC to relevant DOH guidance documents (e.g., DOH regulatory standards, DOH Hospital Modernization Plan) to ensure compliance with all necessary resource requirements.

F. The following medical devices shall be subjected to the evaluation of HTAC to assess their place in the management of conditions for which they have been proposed to be intended following the HTA general criteria as stipulated in the HTA Process Guide. The EAC shall refer the stakeholder to submit an application for such medical device to the HTA General Track Process.
   a. New and potentially innovative medical devices, and new and potentially innovative ancillary devices to existing medical devices (e.g. artificial intelligence, new software) that have been screened but are not part of

standard of care and/or new indications on the use of existing medical devices in the PEMDL which are not yet accepted as standard of care.

b. Existing medical devices that will be used in a population public health screening strategy where either it is a new screening strategy or a different target population is being proposed. For these cases, the medical devices are not the topic for assessment, but the public health screening strategy.

G. The recommendations of the EAC based on its initial screening and evaluation shall be endorsed by the Chairperson of the EAC to the HTAC prior to the conduct of public consultation with DOH Offices and hospitals. The endorsement from the EAC to the HTAC shall include the following: a) letter of endorsement, b) the list of devices proposed to be included in the PEMDL, and c) the references used in the evaluation of the medical devices using the flowchart.

H. The recommendation on the inclusion of medical devices into the PEMDL shall emanate from HTAC.

I. The HTAC recommendation shall be endorsed by its Chairperson to the Office of Secretary of Health. The inclusion of a medical device in the PEMDL shall be considered official once approved and accepted by the Secretary of Health.

III. Process and Methods of Procurement of Devices for Public Health Emergencies

A. As stipulated in AO 2020-0041 titled *The New Implementing Guidelines on Health Technology Assessment to Guide Funding Allocation and Coverage Decisions in support of Universal Health Care,* in the event of a public health emergency as defined in RA 11223 or the Universal Health Care (UHC) Act Implementing Rules and Regulations. the HTAC may do an expedited process of HTA upon the receipt of a written letter from the Secretary of Health.

B. The expedited HTA process for health technologies relevant to public health emergencies are detailed in the HTA Process Guide.

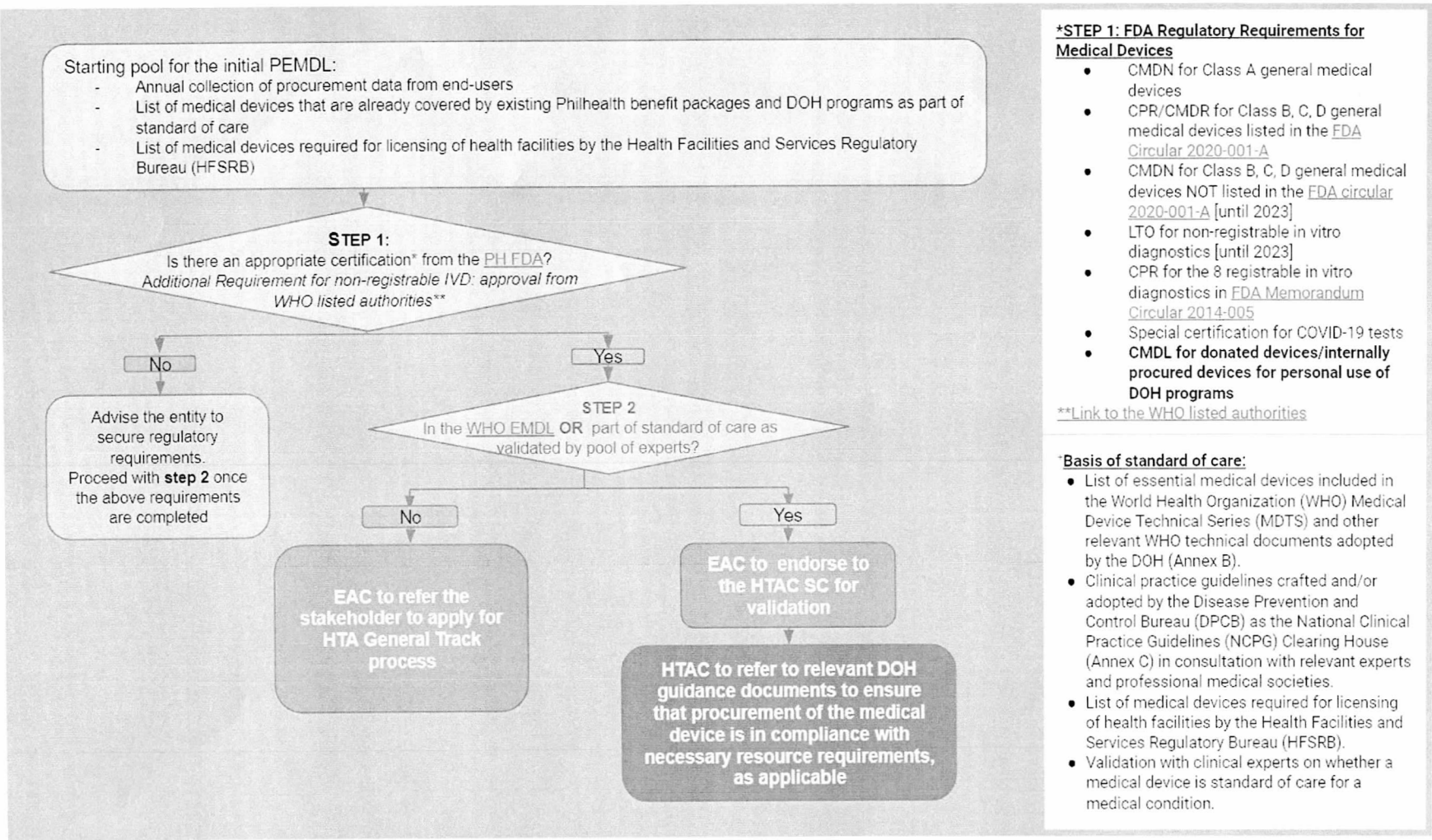
We shall notify our stakeholders once the initial list of medical devices proposed for inclusion into the PEMDL is made available.

Your full cooperation in this endeavor is expected and highly appreciated.

By Authority of the Secretary of Health:

ATTY. CHARADE B. MERCADO-GRANDE
OIC-Undersecretary of Health
Health Regulation Team

Annex A: Flowchart of Selection of Medical Devices and Supplies



Note: The FDA circulars identified in this DM are the current issuances from the Philippine FDA. Please refer to the updated versions of the FDA issuances on regulatory requirements, as it becomes available.

Annex B: List of WHO Published References

1. WHO Technical Specifications for Medical Devices
2. WHO Core Medical Equipment
3. WHO Medical Devices per type of facility
4. WHO List of Priority Medical Devices for Cancer Management
5. WHO List of Priority Medical Devices for Management of Cardiovascular Diseases and Diabetes
6. WHO Technical Specifications of Neonatal Resuscitation Devices
7. WHO Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn, and Child Health
8. WHO Technical Specifications for Oxygen Concentrators
9. WHO Medical Devices and eHealth Solutions Compendium of Innovative Health Technologies for Low-resource settings (2011-2013)
10. Technical specifications of personal protective equipment for COVID-19
11. Priority medical devices list for the COVID-19 response and associated technical specifications
12. PAHO List of Priority Medical Devices for the first level of care for the countries of the Americas
13. WHO: Priority Assistive Products List
14. WHO Systematic review of needs for medical devices for ageing populations
15. WHO compendium of innovative health technologies for low-resource settings (2022)
16. The Selection and Use of Essential In-Vitro Diagnostics

Annex C. List of Published Local CPGs cleared by the DPCB

1. Acute Myeloid Leukemia National Clinical Practice Guidelines (2022)
2. Breast Cancer National Clinical Practice Guidelines (2022)
3. Colorectal Cancer National Clinical Practice Guidelines (2022)
4. Diffuse Large B-Cell Lymphoma National Clinical Practice Guidelines (2022)
5. Philippine Guidelines on Periodic Health Examination (Phase 2) (2022)
6. 2021 Clinical Practice Guidelines on the Management of Hepatitis B in the Philippines
7. Clinical Practice Guidelines for the Diagnosis and Management of Acute Lymphoblastic Leukemia (2021)
8. Philippine Clinical Practice Guidelines for the Diagnosis and Management of Hepatocellular Carcinoma (2021)
9. Philippine Clinical Practice Guidelines for the Diagnosis and Management of Prostate Cancer (2021)
10. Philippine Clinical Practice Guidelines for the Diagnosis, Staging, and Management of Lung Carcinoma (2021)
11. The Philippine Clinical Practice Guidelines on the Diagnoses, Management, Psychosocial Support and Palliative Care of Burkitt Lymphoma in Children and their Families (2021)
12. Philippine COVID-19 Living Clinical Practice Guidelines Phase 1 (2021)
13. Philippine Guidelines on Periodic Health Examination (Phase 1) (2021)
14. The Philippine Interim Clinical Practice Guidelines for the Diagnosis and Management of Well-Differentiated Thyroid Cancer (2021)
15. Update of the Clinical Practice Guidelines on the Diagnosis and Management of Nicotine Dependence (2021)
16. Clinical Practice Guidelines for Management of Dyslipidemia in the Philippines (2020)
17. Clinical Practice Guidelines for Sepsis and Septic Shock in Adults in the Philippines (2020)
18. Clinical Practice Guidelines for the Screening, Diagnosis, Treatment, and Prevention of Neonatal Sepsis (2019)
19. Philippine Clinical Practice Guidelines on Hemodialysis (2018)
20. Clinical Practice Guidelines on Immunization for Women (2017)