Republic of the Philippines
Department of Health
**OFFICE OF THE SECRETARY**

14 September 2022

**DEPARTMENT MEMORANDUM**
**No. 2022 - _____**

**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)**

In accordance with 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*, 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 public 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 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.The proposed medical devices 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 included in the PEMDL or to undergo additional analysis by the HTAC.

B. Only the medical devices included in the full PEMDL shall be procured by DOH health facilities, Offices/Bureaus, and CHDs as stipulated in AO 2021-0038.

C. While the full PEMDL is under development and since the PEMDL (Initial list) is a continuing endeavor that may not have included all medical devices currently being routinely used as part of standard of care by hospitals and other DOH Units/Offices, **procurement by or for DOH hospitals of routine medical devices and equipment currently NOT LISTED in the PEMDL (Initial list) by DOH hospitals SHALL BE ALLOWED until such time that the full PEMDL has been developed by the DOH**, **subject to all of the following conditions:**

    1. A certification from the Chief of Hospital (or equivalent) must be submitted stating that the item/s is/are needed to continue specific medical service/s of the hospital;
    2. The pertinent regulations of the Food and Drug Administration are followed; and,
    3. Government procurement laws and regulations are followed.

## 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 shall emanate from the following:
    1. Annual collection of procurement data from end-users
    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).

E. A medical device that has passed the screening may be recommended to undergo additional analysis on the economic, ethical, legal, social, and health systems impact of the medical device as deemed appropriate by the HTAC.

G. New and potentially innovative medical devices 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 shall be subject 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.

H. 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.

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

J. 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.

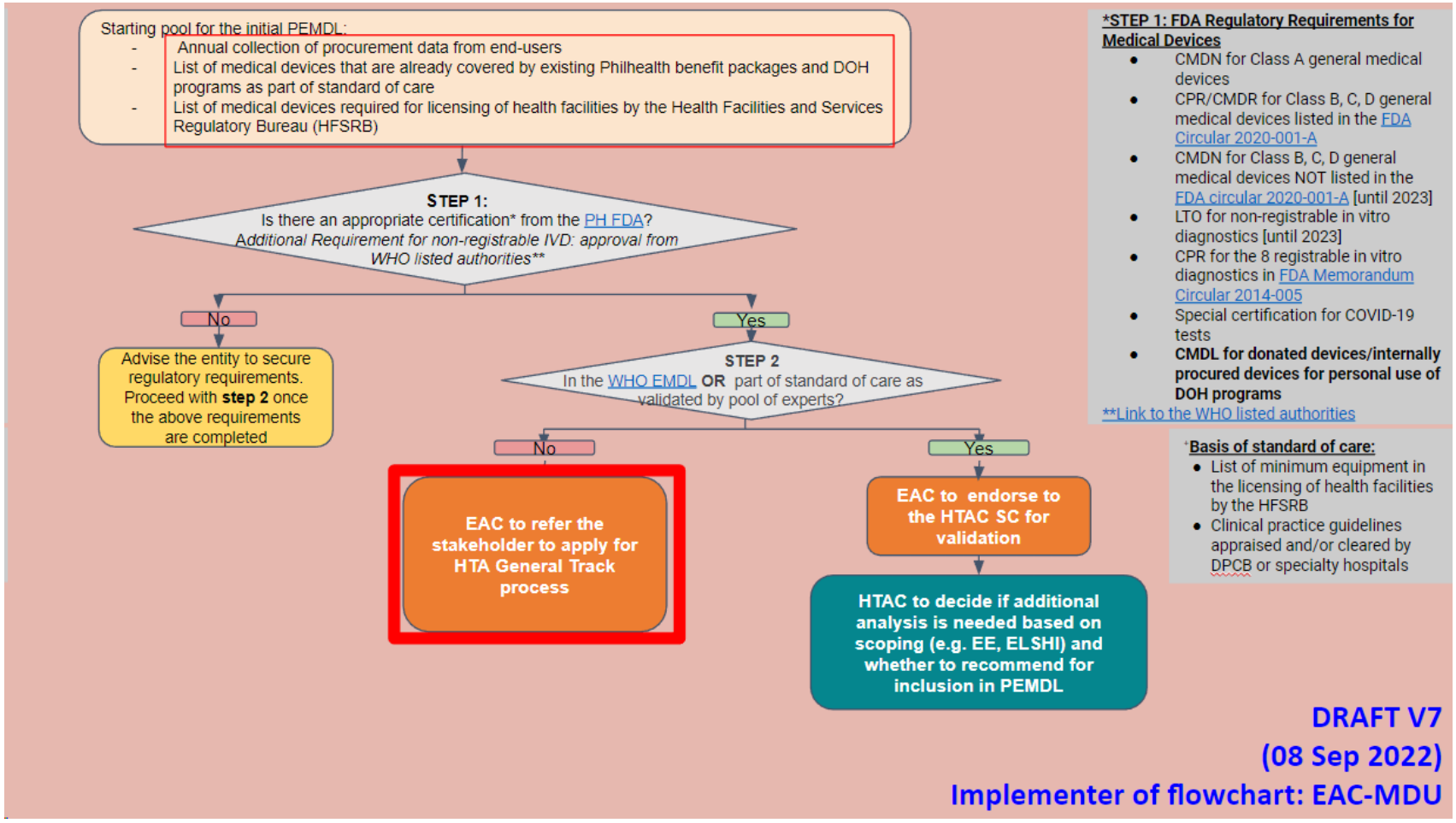
We shall notify our stakeholders once the initial list of medical devices proposed for inclusion into the PEMDL is made available.

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



**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 Neonatal Resuscitation Devices
7. WHO Interagency List of Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn, and Child HealthWHO Technical Specifications of Neonatal Resuscitation Devices
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 (2011-2022)
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)
21. 3rd PAPP Update in the Evaluation and Management of Pediatric Community-acquired Pneumonia (2016)