Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 08 2020

ADMINISTRATIVE ORDER
No. 2020 - 0041

SUBJECT: **The New Implementing Guidelines on Health Technology Assessment to Guide Funding Allocation and Coverage Decisions in support of Universal Health Care**

I. RATIONALE

Ensuring Universal Health Care (UHC) in a resource-limited setting faces challenges of dealing with competing public health priority concerns, growing public demand for equitable health services, and proliferating costlier health technologies with promising claims of better health outcomes. Supporting such perplexing tasks is a priority setting mechanism called health technology assessment (HTA) in recognition of the role of evidence-based policy and decision-making. HTA is the systematic process for generating evidence-informed policies on resource allocation decisions in the health sector. It is a multidisciplinary evaluation of the clinical, economic, organizational, social, and ethical impact of implementing a specific health technology or health intervention in a healthcare system.

In 2013, *Republic Act 10606* also known as the *National Health Insurance Act of 2013* mandated the utilization of HTA in guiding the health services coverage of the Philippine Health Insurance Corporation (PHIC or known as PhilHealth). The Department of Health (DOH), through *Administrative Order 2016 - 0034: The New Implementing Guidelines of the Philippine National Formulary System (PNFS)* required that any medicine considered for inclusion in the PNF shall be assessed based on its benefit-risk assessment (safety and efficacy), cost-effectiveness, affordability and public health relevance.

Pursuant to the recently enacted *Republic Act 11223* also known as "Universal Health Care Act", HTA shall be institutionalized as "*a fair and transparent priority setting mechanism for the development of policies and programs, regulation, and the determination of a range of entitlements*" in recognition of the role of evidence-informed policy and decision-making in pursuit of UHC. The Act mandates that "*Every Filipino shall be granted immediate eligibility and access to preventive, promotive, curative, rehabilitative, and palliative care for medical, dental, mental and emergency health services, delivered either as population-based or individual-based health services: Provided, that the goods and services to be included shall be determined through a fair and transparent health technology assessment process*".

In this light, this order is hereby developed to establish the processes and methods, as well as the roles and responsibilities of other offices, agencies and the different stakeholders in relation to the implementation of HTA.

II. OBJECTIVES

A. General Objective:

This Order aims to define the overall institutionalization and implementation framework for HTA through the Process and Methods Guides, as a priority setting mechanism that shall be recommendatory to DOH and PHIC in their coverage and funding allocation for UHC.

B. Specific Objectives:

1. To provide the governance framework for HTA in the Philippines
2. To provide the processes involved in the implementation and governance of HTA through the issuance of the *HTA Process Guide*
3. To describe the methods of conducting assessments that will guide the generation of policy-informed recommendations through the issuance of the *HTA Methods Guide*
4. To define the roles and responsibilities of stakeholders involved in HTA

III. SCOPE AND COVERAGE

This Order shall be applicable to all DOH offices and DOH-attached agencies involved in generating health policy decisions on the purchase and coverage of both new and existing health technologies with the use of PHIC and DOH funds. It shall also be applicable to the entire health sector (both public and private) as relevant participating stakeholders who will be involved in the HTA process implementation.

IV. DEFINITION OF TERMS

A. Health Technology Assessment (HTA)– refers to the systematic evaluation of properties, effects, or impact of health-related technologies, devices, medicines, vaccines, procedures, and all other health-related systems developed to solve a health problem, and improve the quality of lives and health outcomes, utilizing a multidisciplinary process to evaluate the clinical, economic, organizational, social, and ethical issues of a health intervention or health technology (UHC Act)

B. Health Technologies – refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve the quality of lives. (UHC Act Implementing Rules and Regulations)

C. Health Technology Assessment Process Guide – refers to the document that provides the detailed processes involved in the implementation of HTA which are embedded with mechanisms to incorporate the HTA process principles as outlined in the UHC Act. It also covers the operational procedures and governance of the HTAC.

D. **Health Technology Assessment Methods Guide** – refers to the document that provides standard methods of conducting HTA to generate evidence which will become the basis of HTAC recommendations to the decision-makers

E. **Health Technology Assessment Council** (HTAC) – refers to the recommending body composed of health experts created within DOH in a transitory stage, and supported by the HTA Unit in its governance, management, and operations

F. **Proponents** – refers to individuals such as clinicians, healthcare professionals, patients, program managers, or institutions such as public or private health facilities, professional societies, relevant DOH and PHIC offices/units, industry, who nominates a specific health technology topic for public funding or coverage

G. **Conflict of Interest (COI)** – refers to a situation created when persons or entities in the public and/or private sectors involved in making recommendations and decisions have personal, financial or any other interest in the industry involved in the technology. This includes receiving or accepting any favor, offer or contribution, in monetary form or otherwise. (DOH Department Order 2017-0332)

H. **Clinical Practice Guidelines** (CPG) – refers to the standards of clinical care which shall be used for the treatment and management of patients

I. **Drugs** – refer to pharmaceutical products that pertain to chemical compounds or biological substances, other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals as stated in Republic Act 10918 or the Philippine Pharmacy Act of 2016

J. **Vaccines** – refer to preparations of attenuated, live or killed microorganisms, fractions thereof, its products, or synthetic substitutes, that is administered to activate the immune system and thereby prevent or treat disease

K. **Clinical Equipment and Devices** – Refers to medical devices, radiation devices, and health-related devices:

1. *Medical device* – refers to any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software , material, or other similar or related article intended by the manufacturer 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; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but which may be assisted in its intended function by such means.

2. *Radiation device* – refers to an electrical or electronic apparatus emitting any ionizing or non-ionizing electromagnetic or particulate radiation; or any sonic, infrasonic, or ultrasonic wave. It includes ionizing radiation emitting equipment which is not intentionally designed to produce radioactive materials.

3. *Health-related device* – refers to any device not used in health care but has been determined by the FDA to adversely affect the health of the people.

L. Medical and Surgical Procedures – refers to procedures done for the purpose of preventing, diagnosing, measuring, monitoring, or treating injuries or diseases. All procedures can be classified into six major classes namely, 1) propaedeutic procedures, 2) diagnostic procedures, 3) therapeutic procedures, 4) rehabilitative and psychosocial procedures, 5) plastic and reconstructive procedures, and 6) palliative and hospice care procedures. These procedures will be considered Surgical if it involves any manipulation (both invasive and non-invasive) for the purpose of removing, repairing, and/or improving the function of the involved body part/s. Otherwise, they shall be considered as Medical Procedure.

M. Preventive and Promotive Health Services - refers to primordial, primary, and secondary interventions delivered at the individual- or population-based level that aims to maintain a healthy general population and to prevent or mitigate the impact of diseases to individuals before the health effects of the disease has occurred.

N. Traditional and Complementary medicine (T&CM) – merges the terms Traditional Medicine (TM) and Complementary Medicine (CM), encompassing products, practices and practitioners.

The definition of traditional and complementary medicine is as follows:

1. *Traditional Medicine* - refers to the sum total of knowledge, skills and practice on health care, not necessarily explicable in the context of modern, scientific, philosophical framework, but recognized by the people to help maintain and improve their health towards the wholeness of their being, the community, and society, and their interrelations based on culture, history, heritage and consciousness.
2. *Complementary Medicine* - this adopts the World Health Organization's definition of complementary medicine, wherein the term refers to a broad set of health care practices that are not part of the country's own tradition or conventional medicine and are not fully integrated into the dominant health care system. Complementary medicine shall be used interchangeably with the terms alternative medicine and integrative medicine.

O. Other health technologies – refers to a wide range of healthcare products, packages, or systems used to influence health management of a disease or condition by 1) improving access to data or service, or 2) increasing efficiency or impact of the delivery of intended intervention.

These technologies, either used alone or in combination with another health technology, include:

1. Monitoring and tracking products, defined as those that are used for a) maintaining or encouraging a general healthy state or a healthier lifestyle, or b) reducing the risk or impact of diseases or conditions. These products are non-invasive, not implanted, and do not pose a risk to safety of users (e.g., lasers or radiation exposure).
2. Software and applications, defined as those that are not essential for the direct function of a clinical equipment and device.
3. Electronic platforms and interventions, defined by those that aim to transfer, store, convert formats, and/or display data and results. Provided that, these do not provide analysis or interpretation of input data.
4. Telecommunication platforms and interventions, defined as the distribution of health-related interventions through voice, data, electronic messages, written or printed matter, fixed or moving pictures, words, music or visible or audible signals or any control signals of any design and for any purpose by wire, radio or other electromagnetic, spectral, optical or technological means.
5. Artificial intelligence and machine learning systems, defined as the science and engineering of making intelligent machines that uses different techniques such as model-making based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning, to create an algorithm that is either fixed (i.e., function does not change) or adaptive based on input data.
6. Systems services, defined as those that promote timely access to intended intervention by elimination of physical, financial, or transportation access barriers to care.
7. Complex interventions, defined as interventions that contain several interacting components, attributable to the number of interacting components, number and difficulty of behaviors required by those delivering or receiving the intervention, number of groups or organizational levels targeted by the intervention, number and variability of outcomes, and/or the degree of flexibility or tailoring of the intervention permitted.

Provided that, these technologies are not under the scope of other subcommittees. Provided further, in the occurrence of overlapping health technologies, the subcommittee on Other Health Technologies may give expertise advice or opinion to facilitate the assessment. This does not preclude health technologies for similar purposes that may emerge in the future.

P. **Public health emergency** – refers to an occurrence or imminent threat of an illness or health condition that:

1. is caused by any of the following: (1) bioterrorism; (ii) appearance of a novel or previously controlled or eradicated infectious agent or biological toxin; (iii) a natural disaster; (iv) a chemical attack or accidental release; (v) a nuclear attack or accident; or (vi) an attack or accidental release of radioactive materials; and,
2. poses a high probability of any of the following: (i) a large number of deaths in the affected population; (ii) a large number of serious injuries or long term

disabilities in the affected population; (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial harm to a large number of people in the affected population; (iv) international exposure to an infectious or toxic agent that poses a significant risk to the health of citizens of other countries; or, (v) trade and travel restrictions.

Q. Co-dependent technologies- are a combination of two or more health technologies with the aim of improving patient health outcomes. The use of the technologies needs to be combined (either sequentially or simultaneously) to achieve or enhance the intended clinical effect of either technology.

V. GENERAL GUIDELINES

A. All health technologies for preventive, promotive, curative, rehabilitative, and palliative care for medical, dental, mental and emergency health services, that are to be funded by PHIC and DOH, either as population-based or individual-based health services, shall be assessed and recommended through the HTA process.

B. The HTA process shall be institutionalized as a fair and transparent priority-setting mechanism and shall be recommendatory to DOH and PHIC for the development of policies and programs, regulation and the determination of a range of entitlements; provided, that final decisions on coverage and funding allocation shall be based on the positive recommendations of the HTA. This shall involve linking and aligning the HTA process with the process framework of all existing policies/ programs within the DOH and in PHIC that determines, finances, or delivers health services or technologies as part of publicly-funded national programs or covered benefit packages, such as but not limited to the Philippine National Formulary System (PNFS) essential medicines list development, the DOH National Health Programs (NHP) clinical practice guideline development and service delivery, the National Immunization Council's National Immunization Program (NIP), the DOH Health Facilities Enhancement Program (HFEP), and the PHIC benefit package development.

C. The implementation of the HTA shall adhere to the principles of ethical soundness, inclusiveness and preferential regard for the underserved, evidence-based and scientific defensibility, transparency and accountability, efficiency, enforceability and availability of remedies, and due process (defined in the *HTA Process Guide*).

D. Health technologies which are currently covered and shall be approved for coverage through the HTA process shall be subject to, as new evidence arises, reviews and periodic evaluations to ensure that these continue to add values to the system through compliance with the assessment framework.

E. The HTA for prospective coverage and disinvestment decisions (i.e, existing/ covered health technologies) shall follow these steps:

1. Topic Nomination
2. Topic Prioritization
3. Scoping and Protocol Development
4. Topic Assessment
5. Evidence Appraisal

6. Recommendation
7. Resolution
8. Decision
9. Dissemination

F. The *HTA Process Guide* shall provide the details on the operationalization of the HTA process flow, the roles of the different stakeholders in HTA, and relevant forms and template documentary requirements. Please refer to https://rebrand.ly/PHHTAProcessGuide to download the HTA Process guide.

G. The *HTA Methods Guide* shall provide mandatory guidance to researchers in conducting assessments of the prioritized topics and in producing a standardized HTA report that will be appraised by the HTAC to produce recommendations that will inform all public funding, coverage, and disinvestment decisions made by the DOH and PHIC. Please refer to https://rebrand.ly/PHHTAMethodsGuide to download the HTA Methods guide.

H. The HTA implementation shall be governed by the HTAC which shall be composed of the Core Committee and the Subcommittees for (1) Drugs, (2) Vaccines, (3) Clinical Equipment and Devices, (4) Medical and Surgical Procedure, (5) Preventive and Promotive Health Services, and (6) Traditional Medicine, and (7) Other health technologies.

I. The HTAC shall be supported by the Health Technology Assessment Unit (HTAU) with capacities on policy, planning, and evaluation, as well as technical secretariat support.

J. The generation of evidence for the prioritized topics for assessment shall be conducted by the Assessment Teams composed of the PPE unit of the HTAU in collaboration with partner academic institutions, and shall then be appraised by the HTAC, adhering to the *HTA Process and Methods Guides.*

K. In case of co-dependent health technologies, topic prioritization until the appraisal process shall be jointly conducted by the HTAC Subcommittees concerned.

L. Declaration and management of COI shall be mandatory for all individuals and groups involved in the HTA processes. All stakeholders involved shall comply with existing DOH guidelines on the management of COI. (DOH Department Order 2017-0332)

M. Drugs and Vaccines with a positive HTAC recommendation and approved by the SoH shall be included in the latest edition of the Philippine National Formulary, which is the basis of procurement by the government.

N. Within two (2) years of establishment, the HTAC shall review existing health technologies as part of the rationalization of health packages.

O. Within two (2) years from the effectivity of the UHC Law, HTAC shall review health technologies as part of the comprehensive primary care benefit package including outpatient drug benefit and emergency medical services.

P. In the event of a public health emergency, the HTAC may do an expedited process of HTA upon the receipt of a written letter from the Secretary of Health.

Q. Within five (5) years after the establishment and effective operation of the HTAC, it shall transition into an independent entity separate from DOH, attached to the Department of Science and Technology (DOST).

R. To uphold the independence of the HTA process and foster good governance, proponents are prohibited from actively engaging with the HTA Council and HTA unit unless their inputs are sought.

VI. SPECIFIC GUIDELINES

A. Health Technology Assessment Council (HTAC)

1. Pursuant to the UHC Act, the HTAC shall be established and convened by the DOH, in a transitory capacity to:
   a. Facilitate provision of coverage recommendations on health technologies to be financed by DOH and PHIC
   b. Oversee and coordinate the HTA process within DOH and PHIC
   c. Review and assess existing DOH and PHIC benefit packages

2. The HTAC is composed of the:
   a. HTAC Core Committee
      i. The Core Committee is responsible for the development and submission of final recommendations to policy- and decision-makers, based on the evidence appraisal of the different subcommittees.
      ii. The Core Committee is composed of nine (9) voting members, which will elect from among themselves its Chairperson, namely:
         a. public health epidemiologist;
         b. health economist;
         c. ethicist;
         d. citizen's representative;
         e. sociologist or anthropologist;
         f. clinical trial or research methods expert;
         g. clinical epidemiologist or evidence-based medicine expert;
         h. medico-legal expert; and,
         i. public health expert.

   b. HTAC Subcommittees
      i. The HTAC Subcommittees support the HTAC Core Committee in achieving a timely, effective, efficient, and responsive operational processes by performing the initial prioritization of topics, supervising the assessment teams from scoping to assessment, and performing initial appraisal to develop recommendations.

ii. The HTAC Subcommittees are constituted according to the broad type of health technologies which include: Drugs, Vaccines, Clinical Equipment and Devices, Medical and Surgical Procedures, Preventive and Promotive Health Services, Traditional Medicine and Other health technologies. All subcommittees shall have a minimum of one (1) and a maximum of three (3) non-voting members for each subcommittee.

3. The DOH employs an open nomination, competitive selection, and deliberate recruitment of known and respected experts in relevant fields through a public call for nomination to the academe, professional organizations as well as organized civil society and patient organizations.

4. All the members of the HTAC are selected by the DOH Selection Committee on the basis of the following criteria:
   a. with known integrity and high ethical standards;
   b. known and respected in their fields of expertise;
   c. work experience in technology appraisal and assessments, and
   d. willingness to disclose and adhere to DOH rules on COI management.

5. The Secretary of Health appoints the Chair and members of the Core Committee as well as members of the subcommittee for a term of three (3) years, except for the medico-legal expert, ethicist, and the sociologist or anthropologist, who shall serve for a term of four (4) years. Each member is only allowed to serve not more than three (3) consecutive terms. The DOST Secretary shall appoint the HTAC members upon its transition into an attached agency under DOST.

6. The HTAC and HTAU shall be guided with a Code of Conduct in the execution of its functions.

7. The members shall be entitled to receive honoraria in accordance with existing policies and guidelines.

8. The HTAC core and subcommittees shall meet based on the process flow following the regular cycle of HTA process implementation (refer to *HTA Process Guide*).

9. The HTAC may call upon Technical Resource Persons as regular or by-invitation resource persons rendering their expertise relevant to the evaluations.

B. Technical Resource Persons

1. Technical resource persons are non-voting relevant experts, stakeholders and representatives which may be called upon by HTAC to provide expert opinion with respect to a particular topic assessment in support of evidence appraisal.
2. Regular resource persons include representatives from the Legal Service of the DOH, PHIC, Food and Drug Administration (FDA), Philippine Institute of Traditional and Alternative Health Care (PITAHC), patient groups, and clinical medicine experts.

3. By-invitation resource persons consist of representatives from the private sector and health care providers.
4. All Technical Resource Persons shall be subject to the same Conflict of Interest disclosure and COI management requirements as regular HTAC members to ensure transparency and objectivity in the recommendations made.

C. Health Technology Assessment Unit (HTAU)

1. The HTAU shall be created in support of HTA institutionalization and implementation and shall be composed of the Technical Secretariat team and the Policy Planning and Evaluation (PPE) team.
2. The HTAU Technical Secretariat team shall provide the HTAC the proper support and resources for discharging its duties under the UHC Law including the conduct of needed orientation and training programs for newly-appointed members of the HTAC. Its specific functions and responsibilities are detailed in the *HTA Process Guide*.
3. The HTAU PPE unit shall be responsible for the overall management and conduct of the health technology assessment including internal assessments especially when immediate policy advice is needed, the development of normative guidelines and engagement with stakeholders at all stages of the appraisal. Its specific functions and responsibilities are detailed in the *HTA Process Guide*.

D. HTA Research Network

1. A network of research partners shall be formed jointly by DOH and DOST to support the activities of HTAU.
2. This network aims to (a) implement a research agenda related to HTA, and (b) conduct trainings, workshops, and other activities to build capacity in conducting assessments.
3. Researchers affiliated with specific universities, colleges, institutions or organizations, whether public or private, included in the said network shall ensure compliance with this Order and shall declare any conflict of interest.
4. The creation and development of the HTA research network shall follow a mechanism agreed upon by DOH and DOST.

E. HTA Process

Key steps in the process flow are briefly described below and are detailed in the *HTA Process Guide*.

1. **Topic nomination** –the process of referring topics to HTAC for which technology appraisals may be produced and disseminated for the guidance of policy-makers in healthcare coverage decisions and to health providers and patients on the optimal and appropriate use of health technologies. The HTAU Secretariat manages the process of accepting potential topics for assessment and appraisal by HTAC from health technologies referred by the different Offices of the DOH and PHIC as well as those deemed important by other stakeholders such as professional health organizations, industry, patient organizations, public and private hospitals and therapeutic committees (i.e. for medicines) and local government units through the provincial/city health officer. The topic submission forms are available in the Annex of the *HTA Process Guide*.

2. **Topic prioritization** - the selection of topics through a standard set of prioritization criteria by HTAC to ensure that the appraisal process responds to the priority health care needs of the country and that the topics address conditions that are important to patients, health care providers, PHIC, and DOH program managers, hospitals and local health system administrators. The objective of this specific step in the process is to ensure that topics are subjected to a standard selection process in deciding which health technologies undergo assessment and appraisal to maximize the use of available resources. Through this step, it is also aimed that all relevant stakeholders are properly consulted in a transparent, inclusive and predictable manner. Stakeholders may submit comments on the priority list subject to consideration of HTAC as stated in the *HTA Process Guide.*

3. **Scoping and Protocol Development**- refers to the process of defining the overall scope of the technology assessment in terms of at least five major components:
    a. population of patients who will benefit from the intervention
    b. health technology or intervention of interest
    c. appropriate comparators relevant to the local practice or context
    d. clinically meaningful outcomes
    e. study design
    f. any other consideration that will likely impact the results of the assessment such as appropriate perspective, equity/legal/social issues, time horizon for the analysis, among others

4. **Assessment** - the application of formal scientific methods of evidence synthesis to assess the clinical, economic, health system, ethical, legal, and social impact of covering or disinvesting a particular health technology in the local Philippine context. The standards for assessment as well the guidance in producing the assessment report is detailed in the *HTA Methods Guide.* In the process of assessment, protocol development shall be done by the Assessment Team which includes scoping with relevant stakeholders to refine and validate the assessment methods and scope. The relevant HTAC subcommittee shall review the consistency of the protocol with the agreed methodological standards and set the prescribed timeline of assessment, prior to the approval of the protocol.

5. **Evidence appraisal** - the process by which the HTAC evaluates and makes a judgement on the value of a health technology in the Philippine context using its established criteria based on the evidence presented by the Subcommittees supported by the HTA output of the Assessment Teams

6. **Recommendation** – the process by which the HTAC develops their recommendation to the decision-makers through a deliberative process of assessing the quality and the strength of the evidence. The recommendations of the HTAC Core Committee may be *approve, approve with restrictions/conditions of use*, or *disapprove.* In the event that the HTAC Core Committee finds that the health technology is not affordable to DOH or PHIC, this shall be referred to the DOH Price Negotiation Board (PNB) for their

appropriate action. For health technologies with cost issues, final recommendation shall be withheld until settled by the PNB. The details of the price negotiation process shall be stipulated in a separate issuance by the PNB.

The following decision framework shall be considered by the HTAC in generating evidence-informed recommendations to the DOH and PHIC on the financing or coverage of assessed health technologies:

a. Responsiveness to magnitude, severity and equity - The health intervention must address the top medical conditions that place the heaviest burden on the population, including dimensions of magnitude or the number of people affected by a health problem, and severity or health loss by an individual as a result of the disease such as death, handicap, disability or pain and conditions of the poorest and most vulnerable populations
b. Safety and effectiveness – The intervention must be shown to be safe and effective as shown by systematic reviews and/or meta-analysis or the best source of available clinical evidence. For drugs, the clinical benefit and safety must be demonstrated through Phase IV clinical trial. For non-drug interventions where clinical trials are not practical to conduct, sources of evidence may be observational studies and real world evidence. The intervention must not pose any harm to the users and health care providers that would outweigh the benefits they provide.
c. Household financial impact - The intervention must reduce out-of-pocket expenses. Interventions must have economic studies and cost of illness studies.
d. Cost-effectiveness - The intervention must provide overall health gain to the health system and outweigh the opportunity costs of funding other health technologies. It must represent a more efficient use of health care resources compared to the alternative health technologies.
e. Affordability and Viability - The intervention must be affordable and the cost thereof must be viable to the financing agents. The intervention must be feasible to implement and adopt given existing health care resources at the local or national level.

7. **Resolution** – the process where all stakeholders are allowed to submit any comments, appeals, or requests for reconsideration from the receipt of the initial negative recommendation of HTAC. The appeals may be based on grounds of new evidence that was not part of the initial submission and may impact the recommendation of the HTAC. The full details are stipulated in the *HTA Process Guide.*

8. **Decision** – the process of decision-making based on transmitted recommendation of the HTAC to the Secretary of Health for interventions which fall under the remit of specific health programs at the DOH, and the PHIC Board of Directors for health interventions that are part of the benefit packages of PHIC for final decision-making. Any appeal on a negative coverage decision based on a positive recommendation by the HTAC Core Committee shall be directed to the Secretary of Health or the PHIC Board of Directors for resolution.

9. **Dissemination** – the process of publishing communication materials, policy briefs and evidence summaries for healthcare professionals, patients, and policy makers on the appropriate use of health technologies based on the appraisal and recommendations of the HTAC Core Committee.

F. Legal Protection

All official actions of the HTAC shall be supported by appropriate legal staff as deemed necessary.

VII. ROLES AND RESPONSIBILITIES

A. Office of the Secretary

1. The Secretary of Health shall make the final decisions on health technologies for DOH funding allocation based on positive recommendations as endorsed by the responsible HTAU Cluster Head.

B. PHIC Board of Directors

1. The PHIC Board of Directors shall make the final decisions on health technologies for inclusion in PHIC benefit packages based on positive recommendations as endorsed by the responsible HTAU Cluster Head.

C. Department of Science and Technology

1. Ensure that HTA is included in the national health research agenda and priority-setting of health research
2. Establish an academic network that will support HTA-related activities

D. Department of Health – Health Regulation Team

1. Hire and assign personnel to the HTAU
2. In coordination with the Health Human Resource and Development Bureau, develop and propose to the Department of Budget and Management the creation of plantilla positions for the HTAU
3. Assist in process development of HTA
4. Manage overall HTA process with HTAC and HTAU until transitioned to DOST
5. Endorse HTAC recommendations to the relevant decision-makers

E. Department of Health Bureaus/Offices, such as but not limited to: Disease Prevention and Control Bureau (DPCB), Health Facilities Enhancement Program (HFEP)

1. Propose health technology topics for HTA that needs coverage, expansion, or optimization
2. Provide clinical, epidemiological, cost, program implementation data, and other relevant information upon request which shall serve as inputs in the HTAs
3. Conduct program/ project impact review and operations research of their programs that can help establish real-world evidence of a recommended health technology which can be re-assessed in the future
4. Assist in all matters that will concern HTA

Epidemiology Bureau (EB)

1. Provide up-to-date epidemiological data collected upon HTAC request which shall serve as input in the HTAs
2. Support other HTA activities which are aligned with the mandates and functions of EB

Health Policy Development and Planning Bureau (HPDPB)

1. For proposals involving new health technologies or policies, ensure that budget proposals relative to health services have undergone the HTA process
2. Provide relevant research and policy briefs of DOH commissioned research to HTAC
3. Provide access to research databases
4. Provide assistance in commissioning research for external assessments, as may be needed
5. Support other HTA activities which are aligned with the mandates and functions of HPDPB

Department of Health- Legal Service

1. Provide inputs on legal matters pertaining to the assessment on health technologies
2. Provide legal assistance and representation at any stage of the HTA program implementation to all members of HTAC, the HTAU teams, which includes the PPE and Technical Secretariat.

Price Negotiation Board

1. Coordinate with the HTAC in determining the clinical and economic value of new health technologies as one of the bases of price negotiation arrangements with the industry

F. Food and Drug Administration

1. Share relevant clinical evidence with the HTAC on the safety and efficacy of medical products under its jurisdiction including pre-marketing and post-marketing regulatory assessments

G. Philippine Health Insurance Corporation (PhilHealth)

1. Provide/ share relevant health outcomes, costing and data collected from their monitoring and evaluation of their program implementation.
2. Implement approved health technologies by designing benefit packages
3. Submit and recommend topics for prioritization based on national health strategies and directions

H. Philippine Institute of Traditional and Alternative Health Care (PITAHC):

1. Provide or share relevant traditional medicines health outcomes, costing and data collected from research/ studies/ documentation funded or conducted
2. Coordinate with HTAU on the validation of the certification submitted by the proponents, as part of the documentary requirements for the Subcommittee on Traditional Medicine

VIII. TRANSITORY PROVISION

Within one (1) year from the effectivity of this policy, all responsible DOH offices and DOH-attached agencies shall release new or updated issuances, convene the HTAC, and operationalize the provisions of this issuance and the *HTA Process* and *Methods Guides*.

IX. FUNDING SOURCE

The budget for the implementation of the HTA process framework shall be derived from the funds of the DOH HRT until the HTAU is officially created with a separate line item budget.

X. REPEALING CLAUSE

All previous Orders inconsistent in part or in whole to this Administrative Order are hereby rescinded or amended accordingly.

XI. EFFECTIVITY

This Order shall take effect immediately.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

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SEP 09 2020
MARIA CRISTINA P. RIVERA
KMITS - RECORDS SECTION
Department of Health