

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

MAR 0 9 2022

ADMINISTRATIVE ORDER No. 2022 - <u>0005</u>

SUBJECT: <u>Omnibus Guidelines on the Implementation of the National Deployment</u> and Vaccination Plan (NDVP) for COVID-19 Vaccines

I. RATIONALE

The Department of Health (DOH), together with its line agencies, has been proactive in developing policies that guide government sectors, non-government organizations (NGO), and private entities in the implementation of various efforts for COVID-19 vaccination. As new evidence emerges and various decisions at different levels are made daily, there is a need to align policy directions towards ensuring timely, effective, and coordinated response for COVID-19.

Through the course of the implementation, developing challenges have necessitated a sustained updating and revisions of policies and guidelines. The evolution of policy decisions was brought about by evidence-based information and regular consultations with technical experts. These expert groups include the interim National Immunization Technical Advisory Group (iNITAG), Technical Advisory Group for COVID-19, Health Technology Assessment Council (HTAC), National Adverse Event Following Immunization Committee (NAEFIC), and the Department of Science and Technology (DOST) - Vaccine Expert Panel (VEP).

In anticipation of the transition from the current State of National Public Health Emergency (Proclamation No. 1021, s. 2020) and State of National Calamity (Proclamation No. 1218, s. 2020) towards a declaration of COVID-19 endemicity, the Department of Health (DOH) shall proactively develop and anchor policies that guide government sectors, non-government organizations (NGOs), and private entities, including, but not limited to, Ambisyon 2040, Philippine Medium-Term Development Plan, Universal Healthcare Act, and FOURmula One Plus for Health (F1 Plus), and National Action Plan on COVID-19 (NAP) Phase 4 to 5 towards the facilitation and endorsement of complete staff work for the next government administration, to ensure the operationalization and implementation of Republic Act No. 11525 otherwise known as the COVID-19 Vaccination Act of 2021. Thus, this Omnibus Guidelines on the Implementation of the National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines shall serve as a consolidation of all the COVID-19 policies and issuances.

II. OBJECTIVE

This Order aims to provide a consolidated reference of policy directions for the implementation of the National COVID-19 Vaccine Deployment and Vaccination Program.

III. SCOPE

This Order shall apply to all entities involved in the implementation of the National Vaccine Deployment and Vaccination Program, both from public and private sectors, including all national government agencies (NGAs), local government units (LGUs), development partners, civil society organizations, private sector, and all others concerned.

IV. DEFINITION OF TERMS

- A. Additional Dose refers to a dose which would be needed by vulnerable populations as part of an extended primary series for target populations whose immune response rate following the standard primary series is deemed insufficient by emerging evidence and as indicated in the Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA). The objective of an additional dose in the primary series is to optimize or enhance the immune response in order to establish a sufficient level of effectiveness against disease. In particular, immunocompromised individuals often fail to mount a protective immune response after a standard primary series, but also older adults may respond poorly to a standard primary series.
- B. Adverse Events Following Immunization (AEFIs) refer to any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease.
- C. **Booster Dose -** refers to doses administered to a vaccinated population that has completed a primary vaccination series, when, with time, vaccine effectiveness has fallen below a rate deemed sufficient in that population, as indicated in the EUA issued by the FDA. The objective of a booster dose is to restore vaccine effectiveness from that deemed no longer sufficient.
- D. Causality Assessment refers to a systematic review of data regarding AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received.
- E. Cold Chain refers to a system used for keeping and distributing vaccines in good condition. The cold chain consists of a series of storage and transport links that are all designed to keep vaccines within an acceptable temperature range until they reach the user.
- F. Fully Vaccinated refers to those who have received their complete primary series based on any of the following:
 - 1. Emergency Use Authorization (EUA) List, Compassionate Special Permit (CSP), or other authorizations issued by the Philippine Food and Drug Administration (FDA);
 - 2. Emergency Use Listing of the World Health Organization (WHO).
- G. Injection Safety refers to the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment, and correct disposal of contaminated infection equipment
- H. Partially Vaccinated Individual refers to the individual given with one dose of a twodose series only.

- I. **Primary Vaccination Series -** refers to the number of doses as prescribed in the product-specific EUA provided by the FDA:
 - 1. More than or equal to 2 weeks after having received the second dose in a 2-dose series;
 - 2. More than or equal to 2 weeks after having received a single-dose vaccine;
 - 3. Initial series and an additional dose as authorized by the FDA, such as for adults with comorbidities in immunocompromised states who are medically indicated to receive homologous or heterologous additional doses as part of the primary series.
- J. Serious Adverse Effects (SAE) refer to serious AEFIs that upon causality assessment are classified as a "vaccine product-related reaction" or "vaccine quality defect-related reaction", arising from the use of COVID-19 vaccine. Serious AEFIs may be defined as the following:
 - 1. AEFIs that result in any of the following outcomes death, qualified hospitalization or prolongation of an existing hospitalization, persistent or significant disability or incapacity, and congenital anomaly or birth defect;
 - 2. AEFIs that may be severe, critical, or life-threatening;
 - 3. AEFIs that require intervention to prevent any of the above-mentioned outcomes
 - 4. AEFIs that are classified by the Department of Health, as recommended by the National AEFI Committee (NAEFIC), are a medically important event or reaction.

V. GENERAL GUIDELINES

- A. Implementation of the National COVID-19 Vaccine Deployment and Vaccination Program shall ensure alignment to the general guiding principles of providing safe, effective, and free vaccines for all Filipinos, reducing severity of disease and death, towards economic recovery and restoration of normalcy.
- B. The National COVID-19 Vaccine Deployment and Vaccination Program shall be anchored on the four goals of the COVID-19 vaccination program indicated in the World Health Organization COVID-19 Vaccination Roadmap:
 - 1. To minimize deaths, severe disease and overall disease burden;
 - 2. To curtail the health system impact;
 - 3. To fully resume socio economic activity; and
 - 4. To reduce the risk of new variants
- C. The allocation of COVID-19 vaccines and prioritization of COVID-19 vaccination across all concerned stakeholders shall be anchored on the following principles:
 - 1. **Human well-being**: where human well-being including health, social and economic security, human rights and civil liberties, and child development shall be protected and promoted.
 - 2. Equal respect: where all human beings are recognized and treated with equal moral status and their interests as deserving of equal moral consideration.
 - 3. Global equity: where equity in vaccine access is ensured and shall benefit globally among people living in all countries, particularly people living in low- and middle-income countries.
 - 4. **Reciprocity**: where obligations of reciprocity to individuals and groups within countries bearing significant additional risks and burdens of COVID-19 response for the benefit of the society are honored.

- 5. Legitimacy: where global decisions on vaccine allocation are made, as well as national decisions on vaccine prioritization through transparent processes based on shared values, best available scientific evidence, and appropriate representation and inputs by affected parties.
- D. COVID-19 Vaccination targets
 - 1. The National COVID-19 Vaccine Deployment and Vaccination Program (NVDP) Targets shall aim to provide primary and booster/ additional dose vaccination for all eligible populations allowed in the EUA or authorizations of the FDA.
 - 2. For supply planning and negotiations, target supplies shall cover 100% of all eligible individuals based on the Philippine Statistics Authority's population estimates, encompassing primary, additional, or booster dose vaccination based on the approved EUA. Quantity of vaccines may be adjusted accordingly based on operational constraints.
 - 3. For operational planning, the targets for the primary, additional, or booster dose vaccination shall be on a phased targeting approach per age group.
 - 4. The national government shall continue to implement COVID-19 vaccination even with full market authorization prioritizing the most vulnerable and high risk priority group and include COVID-19 vaccination under the National Immunization Program across all relevant life stages.
- E. Together with COVID-19 vaccination, implementation of the Prevention, Detection, Isolation, Treatment, and Reintegration Strategies shall remain the cornerstone of response to prevent further transmission, and shall be a shared responsibility of the national government, local government units (LGUs), private sector, and the public.
- F. COVID-19 vaccines shall remain as a public good and shall be made available to all Filipinos and all members of the society.
- G. The vaccination of COVID-19 vaccines shall be voluntary in nature and shall not be made mandatory for all Filipino citizens.
- H. AEFI surveillance and response shall take on a whole-of-nation and government approach which places responsibilities to all levels and types of stakeholders. To ensure holistic actions and responses from detection to feedback of AEFI cases including efficiency of investigations, all sectors of the government and community shall have an active role in the surveillance, monitoring, and promptly responding of AEFIs.
- I. Funding for the travelling expenses of the staff of NGAs and other entities who would be volunteering for the conduct of National Vaccination Days shall be ensured by their sending agency and if travel are cancelled due to force majeure, reimbursement scheme shall be applied following the usual accounting rules and regulations.

VI. SPECIFIC GUIDELINES

A. COVID-19 Vaccination Prioritization Framework

1. The COVID-19 Prioritization Framework shall be based on recent developments regarding global vaccine supply, evidence-based data, and continuous consultations

with independent expert groups and other relevant stakeholders, and shall be used to address instances of limited vaccine supply and the competing global demand.

- 2. Even with the sufficiency of vaccine supply, the Prioritization Framework shall be followed in allocation decisions for the rollout of primary dose series booster/additional doses for the eligible population.
- 3. The rollout of COVID-19 vaccination, whether utilization of donated, procured, or sourced through tripartite agreements COVID-19 vaccines, shall follow the phase implementation approach as determined utilizing the Prioritization Framework. Therefore, LGUs and private sector that entered into tripartite agreements shall abide by all relevant policies.
- 4. Individuals with legal residency status in the Philippines (i.e. foreign nationals, diplomats) shall be included in the priority group appropriate to their circumstance. For example, said individuals meeting the eligibility criteria for Priority Group A2 (senior citizens), Priority Group A3 (adults with controlled comorbidities), and the like shall register with their respective local government units (LGU) subject to supply availability.

B. Vaccine Portfolio

- 1. All eligible Filipinos shall receive a primary vaccination series, additional dose, or booster dose consistent with the Emergency Use Authorization (EUA), Certificate of Product Registration (CPR), or other relevant regulatory authorizations issued by the Philippine Food and Drug Administration (FDA) on its safety and efficacy.
- 2. The NVDP shall adopt future EUA or regulatory amendments from the FDA. Clarificatory guidelines and policies may be issued by the Public Health Services Team and National Vaccines Operations Center as deemed appropriate.
- 3. COVID-19 vaccines authorized with EUA for administration as primary series and additional/ booster dose are as follows, and may be updated based on future amendments (Please see Annex A for the complete description of each vaccine):
 - a. SARS-CoV-2 Vaccine (Vero Cell), Inactivated [Coronavac]
 - b. ChAdOx1-S[recombinant] (COVID-19 Vaccine AstraZeneca)
 - c. Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine (nucleoside modified)
 - i. Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty] 30 microgram/ dose dispersion for Injection(IM)
 - ii. Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty] 10 microgram/ dose concentrate for Dispersion for Injection (IM)
 - d. COVID-19 mRNA Vaccine (nucleoside modified) [COVID-19 Vaccine Moderna]
 - e. COVID-19 Vaccine (Vero Cell), Inactivated [COVID-19 Vaccine Sinopharm]
 - f. COVID-19 Vaccine (Ad26.COV2-S [recombinant "Janssen COVID-19 Vaccine"]
 - g. Gamaleya (Sputnik V Gam-COVID-Vac) COVID-19 Vaccine
 - h. Gamaleya Sputnik Light COVID-12 Vaccine
- 4. Adult vaccine recipients and other age groups to be authorized to receive a single dose of COVID-19 vaccine of either a homologous or a heterologous booster or additional dose depending on the eligibility shall be in the following intervals:

- a. At least three (3) months after the completion of the primary dose series of the following vaccines: Pfizer-BioNTech, Moderna, Sinovac, Gamaleya, AstraZeneca and Sinopharm COVID-19 vaccines; and
- b. At least two-three (2-3) months after the completion of the primary dose series of AD26.COV2.s (Janssen) COVID-19 vaccine.
- 5. Further guidelines on implementation of additional/booster shots are provided in Department Memorandum No. 2021-0484, Department Memorandum No. 2021-0494 and subsequent amendments.
- 6. The expansion of eligibility for additional doses or booster vaccination of other COVID-19 vaccine products shall be based on future amendments to the EUA or other authorizations of the FDA.
- 7. Heterologous vaccination of the COVID-19 primary series may be allowed in light of supply and availability issues encountered in the rollout of the COVID-19 vaccination program,

C. Procurement and Donation

- The DOH in cooperation with any NGA, LGU or the private entity shall be authorized to procure COVID-19 vaccines, including goods and services necessary for their storage, transport, deployment, and administration through the Negotiated Procurement under Emergency Cases modality pursuant to Sections 3, 4, 5 and 6 of the Republic Act 11525 otherwise known as The COVID-19 Vaccination Program Act of 2021, with Section 53 (b) of RA No. 9184 or the "Government Procurement Reform Act" and Section 53.2 of 2016 Revised IRR of RA No. 9184 as supplemental thereto. The multiparty agreement shall be signed by themselves jointly or in cooperation with any NGA or instrumentality or LGU or private entity authorized to procure COVID-19 vaccines.
- 2. Pursuant to Section 6 of RA 11525, the National Government through the DOH, as well as LGUs and private entities, may only procure COVID-19 vaccines that are registered with the Philippine Food and Drug Administration (FDA) as evidenced by a valid Certificate of Product Registration (CPR) or which possess an Emergency Use Authorization (EUA). For this purpose, COVID-19 vaccines which shall be procured by the DOH will be guided by the following:
 - a. Emergency Use Authorization (EUA) based on FDA Circular No. 2020-036 entitled, "Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID 19", and
 - b. Certificate of Product Registration (CPR) based on FDA Circular No. 2021-1719, entitled, ""
- 3. Pursuant to Section 7 of RA 11525, and consistent with RA 11223 or the Universal Health Care Act, notwithstanding any law to the contrary, the Health Technology Assessment Council (HTAC) shall have the authority to make recommendations to the DOH on COVID-19 vaccines based on preliminary data from Phase III clinical trials and World Health Organization recommendations, in the absence of completed Phase III and Phase IV clinical trials: Provided, That the COVID-19 vaccine manufacturer has been issued an EUA by the FDA: Provided further, That the authority granted to

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the HTAC herein shall only be valid for as long as the EUA issued by the FDA is in effect, such that in the event of revocation or cancellation thereof by the FDA Director General, the HTA process shall be terminated regardless of stage, and if it has been completed, the results shall be set aside.

- 4. In the procurement of COVID-19 vaccines, the DOH, in coordination with the Department of Finance and other national government agencies, shall be authorized to negotiate, review, draft and approve relevant legal instruments/ documents (e.g. Non-Disclosure Agreement, Term Sheet, Supply Agreement, Advance Market Commitments, etc.) to ensure that the terms and conditions thereof, in behalf of the National Government, as well as LGUs and other Procuring Entities, including, but not limited to the price and payment terms, will reflect price uniformity and to prevent price competition. Payment for services such as brokerage, storage, handling, and distribution shall be based on services rendered subject to the agreements between the contracting
- 5. The LGUs may procure only in cooperation with the DOH through a multiparty agreement, and the relevant supplies of COVID-19 vaccines through the Negotiated Procurement under Emergency Cases under Section 3 and 4 of RA 11525, with Section 53.2 of the 2016 IRR of RA No. 9184 as supplemental thereto, according to the preconditions specified therein, and other relevant guidelines as may be issued by the GPPB.
- 6. Private entities may procure COVID-19 vaccines only through a multiparty agreement with the DOH and the relevant supplies of COVID-19 Vaccines. Such vaccines shall be used only on employees of the private entity and the employees' designated persons. However, such employees and designated persons are not precluded from receiving their vaccination from the government, using government procured/secured COVID-19 vaccines.
- 7. Companies may procure COVID-19 vaccines on behalf of other companies or entities pursuant to the conditions enshrined in the Multiparty Agreement. The private entities through the Chief Medical Officer shall submit to the DOH a list of all the companies for which they are buying the vaccines, which shall be subject to review and approval. This submission shall include the documentation of their internal arrangements.
- 8. The Private Sector entity may choose a specific LGU as the recipient of their excess or surplus COVID-19 vaccines. However, the private sector is strongly advised to consider the capacity of the recipient to accommodate the vaccines, particularly in the cold chain management and adequacy of Vaccination Teams.
- 9. In case the Private Sector entity has not identified an LGU recipient, it may seek the assistance of the DOH, who shall provide it with a list of LGUs considered as priority recipients under its existing prioritization guidelines.
- 10. In case the Private Sector entity does not have an identified LGU recipient or opted not to choose any of the LGUs from the list of LGUs provided by the DOH, it can directly donate its excess or surplus COVID-19 vaccines to the National Government through the DOH.

- 11. The Private Sector entity may likewise choose to donate its excess or surplus COVID-19 vaccines to another Private Sector entity in the following manner:
 - a. Pure Donation; or
 - b. Conditional Donation with reimbursement at cost as contained in Section V.A.1.vii of the DOH - NTF JMC 2021-002 or the "Operational Guidelines for the Donation and Subsequent Reallocation of Privately-procured COVID-19 Vaccine Doses to the National Government, Local Government Units (LGUs), and other Private Sector Entities"

D. Cold Chain, Supply Management and Logistics Distribution

- 1. Shipment and acceptance of vaccines and ancillary immunization commodities shall follow the Department Memorandum No. 2021-0053 entitled, "Interim Guidelines on the Shipment and Acceptance of the COVID-19 Vaccines and Ancillary Immunization Commodities".
- 2. Vaccines shall be inspected by the DOH Inspection and Acceptance Committee for COVID 19 Vaccines and Related Ancillary Supplies, which was reconstituted through Department Personnel Order No. 2021-0215, upon arrival at the main warehouse facility prior to distribution to vaccination sites. The Inspection and Acceptance Committee shall ensure that vaccines are of good quality upon arrival and that full documentary requirements original or photocopy are present, including but not limited to the shipping documents, invoice, and packing list. Similarly, the Centers for Health Development (CHDs), MOH-BARMM, LGUs, and identified recipients shall assess the quality of vaccines upon receipt.
- 3. Cold chain management requirements shall be maintained from manufacturing, storage, and distribution of vaccines to ensure integrity of vaccine compounds. Vaccine cold chain storage facilities shall be assessed by the Research Institute for Tropical Medicine and Supply Chain Management Service of the DOH. Particular requirements and constraints on temperature maintenance for transport, storage and administration of vaccines shall be maintained.
- 4. As the different types of vaccine require varying temperature storage requirements, (a) ultra-cold (-70°C to -80°C), (b) frozen (-15°C to -25°C), and (c) refrigerated (2°C to 8°C), vaccine-specific policies shall be developed in consideration of differences in handling and storage requirements of vaccines.
- 5. Transport of vaccines and other ancillary commodities shall be assisted by uniformed personnel such as the Philippine National Police (PNP) and others as may be designated to ensure vaccine security.
- 6. CHDs, LGUs, and identified recipients of vaccines and ancillary commodities shall develop their distribution plan appropriate to their situation, including inspection process prior to acceptance and timelines to avoid vaccine spoilage.
- 7. Supply management is vital to operationalize the COVID-19 vaccination program. Supply management consists of four key tasks: (a) forecasting, (b) procurement, acquisition and distribution of supplies, (c) storage and inventory, and (d) stockpiling.

8. With the arrival of large volumes of COVID-19 vaccines in the country, an organized and coordinated process of reverse logistics in all levels of governance must be employed to ensure that all used/damaged COVID-19 vaccines are properly accounted for and matched with the COVID-19 vaccine delivery and inventory pursuant to the Department Circular No. 2021-0439 otherwise known as Operational Guidelines on the Reverse Logistics of COVID-19 Vaccines.

E. Masterlisting, Micro Planning, and Mapping

- 1. Master listing of eligible population, vaccination workforce and implementing units/ vaccination sites; microplanning by all LGU and implementing units; and mapping of vaccination workforce, implementing units and vaccination sites shall be continuously conducted during the COVID-19 vaccination roll-out.
- 2. Vaccination Sites
 - a. A permanent fixed-post vaccination strategy shall be used in the conduct of the COVID-19 vaccination campaign through the COVID-19 Vaccination Implementing Units and Vaccination Sites.
 - i. Off-site or non-health facility-based sites (e.g. schools, gymnasiums, etc) that fulfill guidelines set in the NVDP and subsequent guidelines may operate as a vaccination site, provided they are linked to a licensed health facility (such as public or private hospital or rural health units). The licensed health facility shall assist in ensuring the readiness of vaccination sites, especially regarding the management of Adverse Events Following Immunization (AEFI).
 - ii. Without prejudice to the fixed-post vaccination strategy and the complexity in vaccinating bed ridden senior citizens, the LVOCs may adopt a mobile vaccination strategy where a mobile vaccination and AEFI composite team shall proceed from one (1) house or facility to another to vaccinate bedridden senior citizens. The mobile vaccination and AEFI composite team shall ensure that all steps in the vaccination process shall be strictly followed.
 - b. To provide appropriate access points for special populations (i.e. People Living with HIV (PLHIV) in HIV treatment hubs, TB patients in TB DOTS centers, elder population in nursing homes, cancer patients in cancer clinics, patients in mental health institutions, persons deprived of liberty in closed-setting institutions, etc.) LGUs shall ensure vaccination is conducted or scheduled either in a separate site/ facility to keep privacy and confidentiality of patients, provided that the health facilities have adequate human resource and capability to conduct the vaccination based on the National Vaccination and Deployment Plan.
 - c. As a general principle, LVOCs and partners shall designate a dedicated team/s or designated vaccination sites for 5 to 11-year old children and other groups with different formulation to avoid medication errors given the difference in the product formulation of the pediatric Pfizer COVID-19 vaccines compared to adult formulation Pfizer COVID-19 vaccines.
 - d. The LGUs shall ensure that the vaccination sites can reach all sectors and communities, workplaces, or establishments within one hour of travel from each

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resident. LGUs may facilitate transportation of recipients for hard-to-reach areas of the community provided minimum public health standards are met.

F. Requirement of Medical Clearance

- 1. Only persons with the following comorbidities shall be required a medical clearance and certification from a licensed physician:
 - a. Individuals in immunocompromised state such as those with autoimmune disease, HIV, active cancer/malignancy and are currently undergoing chemotherapy, radiotherapy, immunotherapy or other treatment, who underwent transplant, under steroid medication/ treatment, and bedridden patients, with terminal illness, or with less than six months prognosis shall need medical clearance and certification prior to vaccination.
 - b. Children with comorbidities such as medical complexity, genetic conditions neurologic conditions, metabolic/ endocrine diseases, cardiovascular diseases, obesity, HIV infection, Tuberculosis, chronic respiratory diseases, renal disorders, hepatobiliary diseases, and immunocompromised state due to disease or treatment.
 - c. COVID-19 vaccination during the first trimester of pregnancy shall not be recommended, but may be done for pregnant women at high risk for contracting COVID-19, provided that there is shared decision making between the pregnant patient and the attending physician evidenced through a medical clearance.
- 2. The Medical Certification shall provide information of the vaccine recipient's comorbidity/ies and shall indicate that the vaccine recipient can receive the COVID-19 vaccine after thorough assessment and evaluation on the date of certification.
- 3. Medical certification for pediatric A3 shall be given by the attending pediatrician/physician detailing the comorbidity/ies of the vaccine recipient. It shall be secured prior to the vaccination schedule and shall be presented in the registration area during the vaccination schedule.

G. Vaccination Day Process

- 1. The vaccination site shall ensure the following across all steps in the recommended process flow for vaccine administration from registration, health education, screening, vaccine administration, and post-vaccination monitoring:
 - a. Strict adherence to minimum public health standards shall be implemented, especially on appropriate distancing, adequate ventilation based on threshold set by DOLE Department Order 224-21 otherwise known as Guidelines on ventilation for Workplaces and Public Transport to Prevent and Control the Spread of COVID-19, and administrative controls against crowding;
 - b. Information, Education, and Communication (IEC) materials, such as videos, pamphlets, flipcharts, leaflets, and brochures shall be made available in any area of the vaccination site, especially in the waiting area and post-vaccination monitoring area.
 - c. Priority is provided for the senior citizen; pregnant women and separate lanes for the pediatric population.

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2. Health Education and Informed Consent Area

- a. Depending on the eligibility, vaccine recipients shall submit the necessary documents to the vaccination team.
 - i. Those belonging to the Priority Group A3 including pediatric populations with comorbidities shall provide any of the following proofs of comorbidity:
 - a. Medical certificate from an attending physician issued within the past 18 months
 - b. Prescription for medicines issued within the past 18 months
 - c. Hospital records such as discharge summary and medical abstract
 - d. Surgical records and pathology reports
 - ii. For vaccination of children 17 years old and below, the vaccine recipient shall be accompanied by a parent/guardian at the vaccination site. The following documents shall be presented:
 - a. Proof of filiation or relationship between the child and the accompanying adult or other supporting document proving authority to give informed consent
 - b. Valid identification cards or other proof of identity issued by the government, such as but not limited to Barangay Certification, COMELEC Certification and other documents showing the identity of the person.
- b. There shall be a dedicated health education area for the whole vaccination site where IEC materials shall be made available. A projector shall be set up in this area, or the least, a flipchart for health education purposes.
 - i. The health education and informed consent step can be integrated with other steps of the vaccination process to streamline the processes in the vaccination site.
 - ii. Ensure that a health educator is available at all times to provide vaccine recipients with the necessary information and to answer any questions.
- c. After thorough health education which includes explaining benefits, risks and possible side effects of the COVID-19 vaccines and prior to the vaccine administration, the vaccination team shall seek informed consent/ assent depending on the age of the vaccine recipient.
 - i. Adult vaccine recipients shall sign two (2) copies of the informed consent form. One copy shall be provided to the patient and one to be kept by the vaccination team.
 - ii. For vaccination of children 17 years old and below, the informed consent shall be given and signed by the parent/guardian, and the assent shall be given by the vaccine recipient:
 - a. For children ages 12 17 years old, after thorough health education to both the vaccine recipient and the parent/guardian, and prior to vaccine

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administration, informed consent shall be given and signed by the parent/ guardian and the assent shall be given and signed by the vaccine recipient.

- b. For children below seven (7) years old, no formal assent shall be needed, as long as there is no manifestation of dissent from the child. Documentation of non-dissent shall be required as part of the Informed Assent Form.
- c. For children with ages between seven to eleven (7-11) years old, written assent shall be requested, and documented by the child's signature. A verbal assent shall also be acceptable. Documentation of verbal assent shall be required as part of the Informed Assent Form.
- d. The informed consent process for the pediatric vaccination shall be based under Article 220 of the Family Code, the parents and those exercising parental authority shall have, with respect to their unemancipated children or wards, the right and duty "to enhance, protect, preserve and maintain their physical and mental health at all times" as well as "to represent them in all matters affecting their interests." As such, the vaccine recipient's parent/guardian shall provide the consent before the vaccine recipient shall receive the COVID-19 vaccines, which are still under EUA.
- iii. The signing of another informed consent shall not be required for the administration of the second dose of a two-dose primary vaccination series.
- iv. The health education and informed consent step can be integrated with other steps to streamline the processes in the vaccination site.

3. Health Screening Area

- a. At the screening area, the personnel assigned shall scan the patient's QR or Unique Code. Eligible vaccine recipients shall be clinically assessed for COVID-19 symptoms, comorbidities, and other important clinical information. Contraindications and precautions stated in the EUA of FDA, as well as recommendations from the HTAC, shall be followed for all vaccines.
- b. Health screening shall include the following:
 - i. For the adult population, screening for potential allergies to vaccine components, food, and medicines, pregnancy, vaccination with other COVID-19 vaccine, history of bleeding disorders, possible symptoms of COVID-19 infection, exposure to COVID-19, vaccination with other non-COVID vaccines, pregnancy. Blood pressure measurement prior to vaccination of the adult population shall not be required but can be done at the discretion of the vaccination team in the vaccination sites.
 - ii. For the pediatric population, the screening process for the adult population shall also be followed. Weighing of the pediatric population shall be included in the process for proper computation of appropriate dose of paracetamol to be advised to the parent or accompanying adult, once the vaccine recipient experiences fever after vaccination
- c. The latest health screening form shall be used in screening the eligible vaccine recipients. Forms shall be regularly updated based on latest available evidence and the latest version shall remain publicly available for download.

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- d. Doctors shall be the preferred health screeners for the vaccination program. If there is shortage of medical doctors as health screeners, trained nurses shall be deployed or assigned, under the supervision of the vaccination site supervisor. The screening form may also be accomplished by the vaccine recipients prior to the vaccination day through LGU-facilitated house to house screening or facilitated self-assessment guidance to the public. However, the on-site vaccination team shall validate the content of the forms prior to vaccination.
- e. The vaccination of people falling under the following categories shall be deferred for vaccination until resolution of the following conditions:
 - i. Persons presenting with symptoms such as fever/chills, headache, cough, colds, sore throat, myalgia, fatigue, weakness, loss of smell/taste, diarrhea, shortness of breath/ difficulty in breathing, and rashes shall be referred to a physician for clinical evaluation. These individuals may be vaccinated with the COVID-19 vaccine only after full recovery from the acute illness as certified by their attending physician based on current management guidelines.
 - ii. Vaccination sites shall ensure that only patients presenting with a hypertensive emergency (sBP> 180 and/or dBP >120 plus with signs and symptoms of organ damage) shall be deferred vaccination. Vaccination shall be rescheduled until the condition is clinically controlled. Elevated BP readings without any signs and symptoms of organ damage are not cause for deferral of vaccination. However, individuals with elevated blood pressure not classified as hypertensive emergency must be observed 30-60 minutes after vaccination to monitor for evolving signs or symptoms of hypertensive emergency.
 - iii. Persons who have active COVID-19 infections. However, vaccine recipients who have fully recovered or completed treatment in line with the latest protocols on isolation and quarantine period can be vaccinated, whether for first or second dose, without restarting the vaccine dose schedule.
 - iv. Persons who received a non-COVID-19 vaccine dose less than 14 days after receiving a COVID-19 vaccine dose, to standardize implementation and limit confounding variables during the Adverse Event Following Immunization (AEFI) causality investigations. However, urgent vaccination such as anti rabies, tetanus, or immunoglobulins for animal bite and other life-threatening or critical situations may be done provided that it is a shared decision between the patient and the attending health care professional.
 - v. Pregnant and lactating women shall not be given vaccines contraindicated for this special population. Pregnant and lactating women in their first trimester may be vaccinated provided it is a joint decision by the patient and the attending physician, evidenced by a medical clearance.
 - vi. For vaccine recipients whose second dose shall be delayed due to deferment guidelines, the second dose may be provided immediately after the prescribed periods in the deferment guidelines without a maximum time interval, unless otherwise indicated.

4. Vaccination Administration

a. Specific vaccine administration strategies may be adopted per vaccine following most updated product specifications or clinical practice guidelines that shall be regularly updated based on the best available evidence.

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- b. The following health professionals shall be allowed to serve as vaccinators, provided that they undergo recommended training:
 - i. Medical doctors
 - ii. Nurses
 - iii. Midwives
 - iv. Pharmacists
 - v. Dentists
 - vi. Fourth-year nursing students, postgraduate/undergraduate interns and clinical clerks (with supervision)
- c. At the vaccination administration area, the vaccinator shall:
 - i. Thoroughly review the informed consent, health screening and declaration forms to verify eligibility of the vaccine recipient and ensure that the mentioned forms are properly signed
 - ii. Review the information in the vaccination card (for second, additional, or booster doses) to determine the date and the vaccine brand of the first dose administered, and calculate the dose interval.
 - iii. Verify the vaccine brand and formulation to be administered
 - iv. Prepare and administer the vaccine using the correct technique indicated in vaccine-specific guidance based on its product specifications.
 - v. Record the vaccine administration and other pertinent information in the vaccination card.
 - vi. Prior to inoculation, check the appropriateness of the product for the vaccine recipient and ensure the vaccine to be administered is not expired and has been stored in the appropriate temperature. Strictly comply with the instructions of the product label of the vaccine product. Specific vaccine administration strategies may be adopted per vaccine.
 - vii. Draw vaccines from a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. Multi-dose vials to be used for more than one patient shall not be kept or accessed in the immediate patient treatment area. To prevent contamination of the vial, cleanliness and absence of potentially contaminated equipment shall be ensured at all times.
 - viii. Ensure that vials do not contain any indications of possible contamination and chemical reactions due to mishandling (e.g. discoloration, presence of particulates), as provided in the vaccine-specific policies issued by the DOH. In such cases, these vials shall be disposed following set protocols as outlined in Department Memorandum No. 2021-0031, otherwise known as, Interim Guidelines on the Management of Health Care Wastes Generated from COVID-19 Vaccination.
 - ix. Prepare and disinfect the skin prior to vaccine administration by using the following steps:
 - a. Apply a 60-70% alcohol-based solution (isopropyl alcohol or ethanol) on a single use swab or cotton-wool ball. Do not use methanol or methyl-alcohol as these are not safe for human use.
 - b. Wipe the area from the center of the injection site working outwards, without going over the area.
 - c. Apply the solution for 30 seconds then allow it to dry completely.

x. Administer the vaccine in the intramuscularly, in the deltoid muscle.

5. Post-monitoring area

- a. The vaccination team at the post monitoring area shall be composed of 2 composite team:
 - i. to monitor and provide response: Paramedic/Nurse/Midwife
 - ii. to conduct surveillance: Surveillance Officer/ Nurse/Midwife/Pharmacist
- b. They shall check and ensure the completeness of the contents of the AEFI Kit
- c. The AEFI/ AESI composite team shall monitor the vaccine recipient and observe for any adverse reaction. After the observation, the vaccination team shall provide the following information to the vaccine recipient:
 - i. Signs and symptoms to observe and watch out for
 - ii. Instructions and steps on how to seek clinical care and report AEFI events
 - iii. Use AEFI management pathway
- d. Vaccine recipients who experience AEFI during the post-monitoring period at the vaccination site shall immediately be brought to designated health facilities within their health care provider networks. THe LGU shall ensure capacity of the facilities to provide health care in response to the event and ensure the timely detection, notification, reporting, and investigation of the AEFIs.
- e. The vaccination team shall ensure that the vaccine recipient is essentially well before leaving the vaccination site.
- f. A standardized physical vaccination card shall be given to the vaccine recipient to ensure completion of the vaccination process and to enable monitoring of adverse events. The physical vaccination card shall be printed by the facility/ LGU in line with the printing standards set by the DOH. For those who received their first dose, the scheduled date for the second dose shall be indicated in the second dose box in the physical vaccination card. Vaccination cards shall be made available to non-placebo participants of the Solidarity COVID-19 vaccine trial
- g. Monitoring of AEFI shall be done up to 1 year from date of vaccination through the vaccination site or through the vaccine recipient's primary care providers, in compliance to the standards set forth by the DOH and PhilHealth. All vaccine recipients shall be assigned to a primary care provider for monitoring for at least a year post-vaccination.

H. Adverse Events Following Immunization (AEFI)

- 1. AEFIs that are suspected by a health care provider, patient, or relative to be a suspected adverse drug reaction shall be considered as immediately notifiable health events of public health concern by virtue of Republic Act No. 11332 and its 2020 Revised Implementing Rules and Regulations. All disease reporting units, including health facilities, and vaccination sites shall report all AEFIs suspected to be adverse reactions, regardless of seriousness to the proper reporting platforms completely and accurately.
 - a. The VigiFlow serves as one of the official AEFI surveillance online reporting platforms for COVID-19 vaccines in the Philippines, pending development of a

contextually adapted information system that shall obtain more comprehensive AEFI data. Moreover, the latest COVID-19 vaccine AEFI Case Investigation Form (CIF) shall be the primary document needed to be accomplished for each AEFI case reported. Changes in the maximum timeline of submission of reports from detection may be performed based on prevailing conditions and other relevant updates.

- b. For non-serious cases, the DRU shall submit the accomplished CIF for each case at least on a weekly basis.
- c. For serious cases, including deaths, the CIF for each case shall be reported after the clinical investigation and finalization of the diagnosis has been made.
- d. All mandatory fields in the latest version of the AEFI CIF **shall** be completely and accurately accomplished by the reporter with all pertinent documents attached that support the case. The following AEFI related documents shall be also be attached with the submission:
 - i. Accomplished COVID-19 vaccine AEFI CIF;
 - ii. Vaccination card;
 - iii. Health screening form;
 - iv. All pertinent medical records, including laboratory results;
 - v. Investigation reports;
 - vi. Death certificate or medical autopsy results, if applicable
- e. Reporting serious AEFI shall require approval from RESUs as the "approving authority" prior to submitting to VigiFlow. Failure to comply may have considerable delays on case validation, investigation, and overall processing and progress of the case. The Regional and National AEFI Committees and their respective Secretariat shall reserve the right to return endorsed cases submitted for assessment if essential documents are excluded or absent, or remarks are deemed incomplete or inadequate from the transmitted reports or documents
- 2. Only verified serious AEFI cases with sufficient suspicion affirmed by the provider and/or the vaccine recipient or relative, and cases submitted for processing of the PhilHealth Vaccines Injury Compensation Package (VICP), shall be subjected to a complete AEFI investigation for the possible conduct of a causality assessment. Prioritization criteria of serious AEFI cases that are eligible for investigation and causality assessment shall be subject to the periodic review and guidelines set by the DOH.
- 3. For all AEFI cases that have undergone causality assessment by the NAEFIC, the results of assessment for these cases shall be transmitted to the regions in a line list format with appropriate case codes adhering to data privacy standards.
 - a. The RESU with their LESU shall be in-charge of verbally transmitting the causality assessment results and implications to the select and necessary patient, relative or health care provider, while providing appropriate counselling and crisis communication strategies.
 - b. The RESU shall ensure adequate preparation and training for LESUs and local health officers in communicating the results using the template guides provided and develop other guides, as necessary.

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4. The detection and monitoring of AEFI shall be until one year after the latest vaccine dose for vaccines under EUA, in accordance with the latest WHO COVID-19 Safety Surveillance Manual. All personnel and healthcare providers in vaccination sites, health facilities, and disease reporting units shall be responsible for the detection and recognition of AEFI. They shall exert their best clinical judgment in screening and/or probing the vaccination history of all patients seeking consultation about any AEFI in their health facility regardless of seriousness; classify non-serious and serious AEFI through operational definitions elaborated in succeeding guideline; provide proper assessment and working diagnosis based on current clinical practice guidelines and evolving evidence of COVID-19 vaccine AEFI. The FDA provides a summary of the AEFIs observed for the vaccination program through their website.

I. Indemnification

As stipulated in Republic Act 11525, otherwise known as, "COVID-19 Vaccination Act of 2021" and Philhealth Circular 2021-0007, titled Implementing Guidelines on the Coverage of COVID-19 Vaccine Injury due to Serious Adverse Effects Following Immunization Resulting in Hospitalization, Permanent Disability, or Death under COVID-19 National Vaccine Indemnity Fund (The COVID-19 Vaccine Injury Compensation Package) states that the National Vaccine Indemnity Fund shall be established as a trust fund to compensate any person inoculated through the COVID-19 vaccination program in case of death, permanent disability or hospital confinement for any SAE provided that in case of death and permanent disability, the Philhealth is hereby authorized to pay compensation from the indemnity fund. The National Vaccine Indemnity Fund shall be administered by Philhealth.

J. Data and Record Management

- 1. The following information systems shall be utilized in the implementation of the National COVID-19 Vaccine Deployment and Vaccination Program:
 - a. Vaccination Information Management System (VIMS) contains all the COVID-19 vaccine related information of the vaccine recipient
 - b. Vaccination Operations Reporting System (VORS) a daily reporting system of vaccination accomplishment and inventory
 - c. COVID-19 Bakuna Center Registry (CBCR) a registry of vaccination sites
- 2. LGUs with existing information systems or applications shall connect to national COVID-19 vaccination information systems and coordinate with the DICT. CHDs, through the RVOC, shall assist to facilitate this process.
- 3. Any paper record for individual vaccination including the informed consent form shall be classified as a permanent vaccination record. All health facilities shall have proper storage protocols in compliance to health record management guidelines to ensure safekeeping and data protection.
- 4. Any paper record at vaccination sites shall be under the responsibility of the vaccination site supervisor. The supervisor shall also be responsible for daily reporting in the vaccination quick count.

- 5. All authorized entities that have the mandate or legitimate purpose to process COVID-19 vaccination-related data shall be considered as personal information controllers (PIC). LGUs shall be responsible for the management of all personal data collected from vaccination sites. As PICs, they shall uphold transparency, legitimate purpose and proportionality in all the stages of data processing (i.e., collection, duplication, storage, disposal, etc.). They shall practice the highest applicable protection measures in processing personal and sensitive personal information in accordance with the standards for data privacy and security as prescribed in the Data Privacy Act of 2012; issuances by the National Privacy Commission (NPC) and DICT; and other applicable legislations. At the minimum, CHDs shall enforce the following:
 - a. The designated or appointed Data Protection Officer or Compliance Officer for Privacy, shall be accountable for all data privacy-related activities.
 - b. Privacy Notice or Privacy Policy shall be posted on conspicuous places within the vaccination facility. Paper-based forms used in collecting personal data shall indicate all information needed by the data subject, such as:
 - i. contact information of the data protection officer;
 - ii. data processing that will be done to their personal data; and
 - iii. individuals that will have access to their personal data.
 - c. In case of breach or report of possible breach, units shall be advised to follow the prescribed procedures from NPC Circular No. 2016-03: Personal Breach Management.

K. Vaccine Certification

The DOH shall issue a digital vaccination certificate known as VaxCertPH, free of charge, based on centralized data in the Vaccine Information Management System (VIMS) and in compliance with international standards, including the World Health Organization (WHO) Digital Documentation of COVID-19 Certificates (DDCC): Vaccination Status Technical Specifications and Implementation Guidance, which was published on July 27, 2021. The VaxCertPH shall provide individuals vaccinated in the Philippines with official proof of vaccination that can be domestically and internationally recognized and verified securely using digital technologies. The VaxCertPH is not intended to replace LGU vaccine cards, which are used for tracking vaccinations at the local-level and as a reference to help vaccine recipients obtain a VaxCertPH.

L. Demand Generation and Communications Activities

1. Demand Generation and Communications ensure vaccine confidence guided by the increasing vaccination model of the WHO-established Behavioral and Social Drivers of Vaccination (BeSD) expert group. This model describes the factors that influence motivation (beliefs, perceived risk, and social processes) and practical issues (operations, availability and convenience of getting vaccinated) that affect persons' abilities to act on their motivation.

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- 2. Technical assistance shall be provided to support implementers in the social preparation of the general public and target population groups, aligned with the WHO SAGE roadmap for prioritizing use of COVID-19 vaccines especially for most-at-risk populations through:
 - a. Key messages and Information, Education, and Communication (IEC) materials that advocate for the safety and effectivity of vaccines based on current and emerging evidence,
 - b. Strategic platforms and interventions that optimize traditional and digital media, and both online and community-level platforms,
 - c. Feedback mechanisms to combat misinformation, and
 - d. Crisis communications to mitigate the sensationalization of adverse events following immunization
- 3. The CHDs/RVOC/LVOC shall:
 - a. Disseminate COVID-19 vaccine IEC materials and ensure alignment of localized materials with the *RESBAKUNA: Kasangga ng BIDA* branding guidelines (<u>https://bit.lyResbakunaBrandBook</u>).
 - b. Ensure the functionality of their crisis communications protocols aligned with DM 2021-0224: Interim Guidelines on Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines.
 - c. Update demand generation and communications microplans and recalibrate according to insights from communities, coverage data from LGUs, and operational strategies relevant to the local context to target those remaining unvaccinated, especially vulnerable groups.
 - d. Ensure feedback mechanisms and social listening by a) reporting frequently asked questions, misinformation, and rumors through the bimonthly cascade of CHD Health Promotion Units with the Health Promotion Bureau, b) and promoting the use of the DOH's official KIRA chatbot (https://m.me/OfficialDOHgov) to get vetted information (Magtanong kay KIRA), report fake news and misinformation, and provide citizen feedback (Magreport kay KIRA).
- 4. Vaccination Sites and LGUs shall:
 - a. Utilize the latest messaging house and key messages cascaded by the Health Promotion Bureau and through the weekly demand generation bulletin. They shall ensure that brand-agnostic messaging is maintained at all times, aligned with NVOC Advisory No. 125, and that vaccination should remain apolitical and should not be used as platforms for any campaign-related activities.
 - b. Plan and implement demand generation and communication activities in accordance with the DILG Memorandum Circular 2021-019, entitled "Guidelines on the Implementation of Demand Generation Activities in support to the National COVID-19 Vaccine Deployment Plan" and ensure coverage of all priority population groups.
 - c. Ensure the utilization of both offline and community level social mobilization and demand generation strategies, especially to reach vulnerable populations.
 - d. Provide regular updates to the CHD on targets and coverage data at local level, progress of their microplan, and other collected social listening data. These information shall be used to recalibrate strategies and demand generation and

communications microplans to target those remaining unvaccinated, especially vulnerable groups.

VII. ROLES AND RESPONSIBILITIES

Specific roles and responsibilities shall be established in consideration of devolution and reassignment of roles and functions to different levels of the government.

A. The Food and Drug Administration (FDA) shall spearhead the development and implementation of a comprehensive plan on vaccine safety surveillance for all stakeholders, oversights, and actors;

B. The Department of Health (DOH) shall:

- 1. The Disease Prevention and Control Bureau (DPCB) shall develop plans, policies, programs, projects and strategies, including the national allocation and framework, for all COVID-19 vaccines and provide coordination, technical assistance, capability building, consultancy and advisory services related to COVID-19.
- 2. The **Epidemiology Bureau (EB)** shall support the surveillance, management, monitoring, and evaluation of vaccine safety surveillance for COVID-19 vaccines.
- 3. **Health Promotion Bureau** shall design a demand and risk communication plan; implement advocacy, social mobilization and community engagement activities; provide technical assistance and support to implementers in ensuring the social preparation of target population groups and geographical areas prior to vaccination.
- 4. Supply Chain Management Service shall develop a cold chain and logistics plan to the COVID-19 vaccine for cold chain and logistics management; to facilitate acceptance and inventory of vaccines and logistics and facilitate storage, distribution and delivery of vaccines and logistics to target areas.
- 5. Bureau of International Health Cooperation shall engage and negotiate with international parties and entities on COVID-19 vaccines; provide feedback and updates to the other respective Technical Groups (TG) pertaining to vaccine development in the global market.
- 6. The Field Implementation and Coordination Team (FICT) shall be assigned to lead and oversee the nationwide implementation of COVID-19 vaccination program through the Centers for Health Development. Issuance of advisories through the National Vaccination Operations Center (NVOC). An operations center at the national level can be established under the FICT offices as needed.
- 7. The Knowledge Management and Information Technology Service (KMITS) shall be in-charge of maintenance of infrastructure requirements and provision of IT support for the vaccination program and national COVID-19 vaccine certification turned over to the DOH

- 8. Centers for Health Development (CHD) shall oversee regional implementation of the NVDP, assist through technical assistance, and develop mechanisms to ensure up to date and accurate reporting of performance and implementation issues to the DOH-CO.
- C. Other NGAs may provide support to implement the NVDP for COVID-19 vaccines in line with its objectives.
- D. Local Government Unit (LGU) shall establish local vaccinations operations centers (LVOC) and ensure implementation of all policies of the NVDP. They shall ensure up to date and accurate reporting through establishment reporting platforms.
- E. Private sector partners may provide implementation support to COVID-19 vaccination and the whole of government approach to re-opening the economy, following the NDVP for COVID-19 Vaccines, the provisions set by these guidelines and other relevant policies set by the National Government.

VIII. REPEALING CLAUSE

AO No. 2021-0005, otherwise known as, "National Strategic Policy Framework for COVID-19 Vaccine Deployment and Immunization" and DM No. 2021-0099 titled "Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19" are hereby repealed. All other related issuances such as Department Circular No. 2021-0464, 2021-0464-A, 2021-0483 are hereby revised, modified, or rescinded accordingly. Nothing in this Order shall be construed as a limitation or modification of existing laws, rules, and regulations.

IX. SEPARABILITY CLAUSE

If any clause, sentence, or provision of this Order shall be declared invalid or unconstitutional, the other provisions not affected thereby shall remain valid and effective.

X. EFFECTIVITY

This Order shall take effect immediately after publication to the Official Gazette or a newspaper of general circulation.

TDUQUE, III, MD, MSc

Secretary of Health

Annex A - Prioritization framework

Priority Group	Description				
Eligible Population Group A					
Priority Group A1	Frontline workers in health facilities both national and local, private and public, health professionals and non-professionals like students in health and allied professions courses with clinical responsibilities, nursing aides, janitors, barangay health workers, etc.				
Sub-priority					
A1. 1	COVID-19 referral hospitals designated by the DOH;				
A1. 2	Public and private hospitals and infirmaries providing COVID-19 care, as prioritized based on service capability, starting from level 3 hospitals, to level 2 hospitals to level 1 hospitals, and then infirmaries; Among hospitals with a common service capability, the order of priority shall be from facilities owned by the DOH, then facilities owned by LGUs, and then facilities owned by private entities;				
A1.3	Isolation and quarantine facilities such as temporary treatment and monitoring facilities and converted facilities (e.g. hotels, schools, etc) that cater to COVID-19 suspect, probable, and confirmed cases, close contacts, and travellers in quarantine;				
A1.4	Remaining hospitals including facilities of uniformed services not catering to COVID-19 cases;				
A1.5	Government owned primary care based facilities such as Urban Health Centers, Rural Health Units and Barangay Health Stations, birthing homes, and Local Health Offices to include members of BHERTS, contact tracers, social workers; vaccinators				
A1.6	Stand-alone facilities, clinics and diagnostic centers, and other facilities and health care workers otherwise not specified (e.g. clinics, dialysis centers, dental clinics, and COVID-19 laboratories), dealing with COVID-19 cases, contacts, and specimens for research purposes, screening and case management coordinated through their respective local government units; and				
A1.7	Closed institutions and settings such as, but not limited to, nursing homes, orphanages, jails, detention centers, correctional facilities, drug treatment and rehabilitation centers, and Bureau of Corrections.				
A1.8 (Expanded A1)	Outbound Overseas Filipino Workers (OFW)s for deployment within the next four months				

Table 1. Categories of Priority Populations for COVID-19 Vaccination

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Priority Group	Description					
A1.9 (Expanded A1)	Immediate family members of health care workers which refers to all members 18 years old and and above, of the household where the health care worker lives to include house mates, helpers, and drivers					
Priority Group A2	Senior citizens aged 60 years old and above					
Sub-Priority						
A2.1	Institutionalized senior citizens including those in registered nursing homes and other group homes with elderly working together (e.g. convents).					
A2.2	All other senior citizens, including bed-ridden senior citizens at home. A2 plus one household member shall be in constant close contact with, and/or living in the same household with Senior Citizens.					
Priority Group A3	Adults with comorbidities not otherwise included in the preceding categories.					
	Priority shall be given to adult whose comorbidities are among the top causes of COVID-19 and national morbidity and mortality for prioritization to include chronic respiratory disease, hypertension, cardiovascular disease, chronic kidney disease, cerebrovascular disease, malignancy, diabetes, obesity, chronic liver disease, neurologic disease, and immunodeficiency state.					
	 A sub-group under the Priority Group A3 which needs to secure medical clearance prior to vaccination shall include the following: a. Autoimmune disease b. HIV/Malignancy c. Cancer d. Transplant patients e. Undergoing steroid treatment f. Patients with poor prognosis/Bed-ridden patients 					
Pediatric A3	Comorbidities for the Pediatric A3 needing to secure medical clearance prior to vaccination shall include the following: a. Medical complexity: long term dependence on technical support e.g. tracheostomy associated with developmental delay and/or					
	 genetic anomalies b. Genetic conditions: Down's Syndrome (Trisomy 21), Glucose-6-phosphate dehydrogenase deficiency (G6PD), genetic disorders affecting the immune systems such as primary immunodeficiency disorders, thalassemia, and other chromosomal abnormalities c. Neurologic conditions: Seizure Disorder, Autism Spectrum Disorders (ASDs), Cerebral Palsy, Stroke in the Young, Chronic Meningitis e.g. Tuberculosis, chronic neuromuscular diseases, and chronic demyelinating diseases 					

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Priority Group	Description					
	1. Metabolic/ endocrine diseases: Diabetes Mellitus (DM),					
	Hypothyroidism, Diabetes Insipidus (DI), Adrenal insufficiency,					
	Hypopituitarism, and other hereditary metabolic diseases.					
	e. Cardiovascular diseases: Hypertension, Congenital Heart Diseases (CHDs), Cardiomyopathy, Rheumatic Heart Disease (RHD), Mitral Valve Disease, Pulmonary Hypertension with Right Heart Failure.					
	f. Obesity: BMI > 95th percentile for age and height					
	g. HIV Infection					
	h. Tuberculosis: Pulmonary (collapse/ consolidations, with empyema, and miliary), Extrapulmonary, (pleural effusion, pericarditis, abdominal, genitourinary, central nervous system, spinal column, bone, joint, cutaneous, ocular and breast), and Disseminated (involvement of two (2) or more organs).					
	i. Chronic Respiratory Diseases: Chronic Lung Diseases (Bronchiectasis, Bronchopulmonary Dysplasia, Chronic Aspiration Pneumonia), Congenital respiratory malformation, Restrictive Lung Diseases, neuromuscular disorders, syndromic with hypotonia, skeletal disorders, chronic upper and lower airway obstruction (Severe Obstructive Sleep Apnea, Tracheomalacia, Stenosis, Bronchial Asthma).					
	j. Renal Disorders: Chronic Kidney Diseases, Nephrotic Syndrome, End-Stage Renal Disease (ESRD), patients on dialysis and continuous ambulatory peritoneal dialysis (CAPD), Glomerulonephritis (e.g. lupus nephritis), Hydronephrosis.					
	k. Hepatobiliary Diseases: Chronic Liver Disease, Cirrhosis, Malabsorption Syndrome.					
	 Immunocompromised state due to disease or treatment: Bone marrow or stem cell transplant patients, solid organ transplant recipients, haematological malignancies (leukemia, anemia, thalassemia), cancer patients on chemotherapy, severe aplastic anemia, autoimmune or autoinflammatory disorders requiring long- term immunosuppressive therapy (e.g. Systemic Lupus Erythematosus, Rheumatoid Arthritis), patients receiving immune- modulating biological therapy [e.g. Anti - Tumor Necrosis Factor (TNF), rituximab, among others], patients receiving long-term systemic steroids [> one (1) month], functional asplenia, patients who underwent splenectomy. 					

Priority Group Description					
Expanded A3	Pregnant and lactating women				
Priority Group A4	Private sector workers required to be physically present at their designated workplace outside of their residences; employees in government agencies and instrumentalities, including government-owned and controlled corporations and local government units; and informal sector workers and self-employed individuals who may be required to work outside their residences, and those working in private households.				
A4.1 Private sector workers who work outside their homes					
A4.2 Employees in government agencies and instrumentalities, inc government-owned or controlled corporations (GOCCs) and government units					
A4.3	4.3 Informal sector workers and self-employed who work outside their homes and those working in private households				
Priority Group A5	riority Group A5 Poor population based on the National Household Targeting System for Poverty Reduction (NHTS-PR) or other verification mechanisms of the local government not otherwise included in the preceding categories				
Rest of the Adult Population (ROAP)					
Rest of the Pediatric Population (ROPP)					

Vaccine	Philippine FDA EUA approval	Age group covered by PH FDA EUA	Dose and frequency	Storage requirement	Contraindications
Pfizer BioNTech Comirnaty mRNA	January 14, 2021 May 21, 2021 (expected EUA to include 12-15 y/o)	12 y/o and above	2 doses 21 days apart	-80°C to -60°C for closed lid vial can be stored at 25°C for 5 mins for open lid vial can be stored at 25°C for 3 mins	Hypersensitivity to any component of the Pfizer vaccine such as but not limited to the following: Polyethylene glycol, Polysorbate, mRNA, lipids, Potassium chloride, Monobasic potassium, Phosphate, sodium, Chloride, dibasic sodium phosphate dihydrate, Sucrose.
	December 22, 2021	5 to 11 y/o	2 doses 21 days apart	-90 °C to -60 °C for 6 months	
Oxford AstraZeneca Viral Vector (non- replicating)	January 28, 2021	18 y/o and above	2 doses, 4-12 weeks apart	2 to 8°C	Hypersensitivity to any component of the AstraZeneca vaccine such as but not limited to the following: L- Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate (EDTA)Water for injection.
Sinovac CoronaVac Inactivated Virus	February 22, 2021	18 y/o and above	2 doses 28 days apart	2 to 8°C	Hypersensitivity to any component of the Sinovac vaccine such as but not limited to the following: Disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride.
Gamaleya Sputnik V	March 19, 2021 (with 2nd dose	18 y/o and above	2 doses 21-42 days	-18°C and below (frozen solution)	Pregnant and lactating women Hypersensitivity to any component of the Gamaleya

Annex B. Vaccine Portfolio as of February 10, 2022 (For most updated reference, refer to FDA's List of Authorized COVID-19 Vaccines)

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Vaccine	Philippine FDA EUA approval	Age group covered by PH FDA EUA	Dose and frequency	Storage requirement	Contraindications
Viral Vector (non- replicating)	interval on July 8, 2021		apart		Sputnik V vaccine such as but not limited to the following: Tris hydroxymethyl, Aminomethane, Sodium chloride, Sucrose, Magnesium chloride, Hexahydrate, Sodium EDTA, Ethanol
J&J Janssen Viral Vector	April 19, 2021	18 y/o and above	1 dose	2 to 8°C (3 months)	 Hypersensitivity to any component of the Janssen vaccine such as but not limited to the following: Recombinant, Replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, Citric acid monohydrate, Trisodium citrate, Dihydrate, Ethanol, 2-hydroxypropyl-β-cyclodextrin, Polysorbate-80 sodium chloride)
Moderna mRNA	May 5, 2021	18 y/o and above	2 doses 28 days	-25 to -15°C 2 to 8°C (30days)	Hypersensitivity to any component of the Moderna vaccine such as but not limited to the following: Messenger ribonucleic acid, lipids, Polyethylene glycol, 2000 dimyristoyl glycerol [DMG], cholesterol, 1,2-distearoyl-sn- glycero-3-phosphocholine [DSPC]), tromethamine,Tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, Sucrose
Sinopharm Inactivated Virus	June 7, 2021	18 y/o and above	2 doses 21-28 days apa	2 to 8°C	Pregnant and lactating women Hypersensitivity to any component of the Sinopharm vaccine such as but not limited to the following: Sodium chloride, Disodium, Hydrogen phosphate, Sodium hydrogen, Phosphate Aluminum, Hydroxide Individuals who have had severe allergic reactions to vaccines in the past (such as acute allergic reactions,

Vaccine	Philippine FDA EUA approval	Age group covered by PH FDA EUA	Dose and frequency	Storage requirement	Contraindications
					angioneurotic edema, dyspnea, etc.) Individuals with uncontrolled epilepsy and other progressive nervous system diseases, and individuals with a history of Guillain-Barre syndrome
Sputnik Light Viral Vector	August 20, 2021	18 y/o and above	1 dose	-18 °C to -22°C	Pregnant and lactating women Hypersensitivity to any component of the Sputnik light vaccine such as but not limited to the following: Tris (hydroxymethyl), Aminomethane , Sodium chloride, Sucrose, Polysorbate Magnesium chloride, Hexahydrate – EDTA disodium salt dehydrate, Ethyl alcohol, Ethanol

ANNEX C. Summary of Relevant Materials

Vaccination Day Templates

- Vaccine-specific Health Declaration Screening Form, Informed Consent Form: <u>https://bit.ly/RESBAKUNAVaxSpecific</u>
- Assent Form for Pediatric Vaccination: <u>http://bit.ly/ResbakunaKids_2022</u>
- Medical Certificate for Pediatric A3: <u>http://bit.ly/ResbakunaKids_2022</u>
- Bayanihan Bakunahan materials (may be used for nationwide or region-wide activities): <u>bit.ly/BayanihanBakunahan_2022</u>

Department of Health

- Healthy Pilipinas website: <u>https://healthypilipinas.ph/</u>
- Bida solusyon sa COVID-19: <u>https://bit.ly/BIDAPartners</u>
- COVID-19 case tracker: <u>https://doh.gov.ph/covid19tracker</u>.
- COVID-19 case bulletin: https://doh.gov.ph/bulletin.
- NVOC tracker: https://doh.gov.ph/covid19-vaccination-dashboard.
- Vaccination tracker: https://doh.gov.ph/covid19-vaccination-dashboard
- National Vaccination Operation Center advisories:<u>https://bit.ly/RESBAKUNA_COVID19VaccinesIssuances</u>.
- Health Technology Assessment related documents: <u>https://hta.doh.gov.ph/</u>

Regulatory References

- List of COVID-19 vaccines with Philippine FDA-issued Emergency Use Authorization: https://www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization/
- List of COVID-19 vaccines granted with Emergency Use Listing (EUL) by the World Health Organization: <u>https://covid19.trackvaccines.org/agency/who/</u>
- Status of COVID-19 vaccines within the WHO EUL/ Pre Qualification evaluation process: https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_23Dec2021.pdf
- US FDA references: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Adverse Event Following Immunization Materials

- CIF form: A template of the latest COVID-19 vaccine AEFI CIF: <u>https://bit.ly/aefic19ph</u>
- AEFI Kit
- AEFI Management Pathway: https://bit.ly/RESBAKUNAFactsheets.
- COVID-19 AEFI Trainings and Policies: https://bit.ly/aefic19ph.
- Other assessment and management guidelines for common AEFIs: https://bit.ly/RESBAKUNAFactsheets, as deemed necessary.
- PhilHealth Implementing Guidelines on the Coverage of COVID-19 Injury, due to Serious Adverse Effects (SAEs) Following Immunization Resulting in Hospitalization, Permanent Disability, or Death under the COVID-19 National Vaccine Indemnity Fund (The COVID-19 Vaccine Injury Compensation Package): <u>https://www.philhealth.gov.ph/circulars/2021/circ2021-0007.pd</u>f

Demand Generation Materials

- DOH's Katuwang na Impormasyon para sa Responsableng Aksyon (KIRA) chatbot: <u>https://m.me/OfficialDOHgov</u>
- Materials for Pediatric Vaccination: <u>https://bit.ly/ResbakunaKids_2022</u>
- Summary of offline and community level social mobilization and demand generation strategies: <u>https://bit.ly/RESBAKUNACommunityToolkit</u>
- Demand Generation Playbook: <u>https://bit.ly/RESBAKUNA_DemGenPlaybook</u>
- CHD microplans: <u>https://bit.ly/RESBAKUNA_MicroplanMonitoring</u>
- COVID-19 vaccine IEC materials: <u>bit.ly/Resbakuna_2022</u>