

DEPARTMENT OF HEALTH NATIONAL TASK FORCE AGAINST COVID-19

MAR 2 6 2021

JOINT ADMINISTRATIVE ORDER

No. 2021- DOOL

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SUBJECT: Implementing Rules and Regulations of Republic Act No. 11525 known as "An Act Establishing the Coronavirus Disease 2019 (COVID-19) Vaccination Program Expediting the Vaccine Procurement and Administration Process, Providing Funds Therefor, and For Other Purposes"

I. RATIONALE

The Coronavirus Disease 2019 (COVID-19) pandemic is the toughest global health challenge so far that has affected the whole country and its health system, and strained the resources of the Government. On January 20, 2020, it was declared by the World Health Organization (WHO) as a public health emergency of international concern, and was further declared as a pandemic on March 11, 2020. President Rodrigo R. Duterte issued Proclamation No. 922 declaring a state of public health emergency in the Philippines due to COVID-19. Subsequently, Proclamation No. 929 declared a state of calamity throughout the country due to COVID-19, which was extended by Proclamation No. 1021.

A year after the government declared a state of public health emergency, there are more than 600,000 reported COVID-19 cases and counting. Increasing cases and challenges to mitigate its spread has been compounded by the presence of COVID-19 variants in the country that have made the virus more transmissible. The vaccines developed and their roll-out is envisioned to complement the various measures in place to curb this health crisis. It then becomes imperative to expedite the procurement and administration of safe and effective COVID-19 vaccines.

In view thereof, Republic Act (RA) No. 11525, also known as the "COVID-19 Vaccination Program Act of 2021", herein referred to as the "Act", was signed by President Rodrigo R. Duterte on February 26, 2021. The Act authorizes the National Government, and the Local Government Units (LGUs) to undertake negotiated procurement of COVID-19 vaccines, while the private entities including the Philippine Red Cross are authorized to procure in coordination and cooperation with the DOH and NTF, through the multiparty agreement. It also provides for immunity from lawsuits of certain individuals and includes an indemnity fund to compensate for serious adverse events following immunization (AEFI). The interim Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines was issued in January 2021 to provide the operational guidelines in the implementation of the COVID-19 Vaccination Program.

II. OBJECTIVE

This Order aims to provide the IRR of the Act establishing the COVID-19 Vaccination Program expediting the vaccine procurement and administration process, providing funds thereof, and other purposes.

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III. SCOPE AND COVERAGE

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This IRR shall apply to all concerned DOH Bureaus and Services, Centers for Health Development (CHDs), the Philippine Health Insurance Corporation (PhilHealth) and other attached agencies, Ministry of Health - Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM) pursuant to RA No. 11054, or the "Bangsamoro Organic Law", public and private health facilities, other relevant National Government Agencies (NGAs) who are members of the National Task Force Against COVID-19 (NTF) and instrumentalities such as the Government Procurement Policy Board (GPPB), Interim National Immunization Technical Advisory Group (iNITAG), LGUs, private sectors and all others that are involved in the implementation of the COVID-19 Vaccination Program.

Further, in the spirit of the Act, this covers all procured and donated COVID-19 vaccines with valid Emergency Use Authorization (EUA) from the Philippine Food and Drug Administration (FDA).

IV. INTERPRETATION AND IMPLEMENTATION

This IRR shall be interpreted and implemented pursuant to the Declaration of Policy provided in Sec. 2 of the Act. This subscribes to undertake the COVID-19 Vaccination Program through an integrated approach to health development which shall endeavor to make essential social services available to all people at an affordable cost. The COVID-19 Vaccination Program shall be facilitated, initiated, and monitored by the National Government, through the DOH and the NTF, and other duly constituted authorities and instrumentalities.

V. **DEFINITION OF TERMS**

For purposes of the Act and this IRR, the following terms shall be defined as follows:

- A. Adverse Event Following Immunization (AEFI) refers 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.
- B. Ancillary supplies refer to supplies necessary for the administration of the COVID-19 vaccines such as, but not limited to needles, syringes (auto-disabed, mixing), safety collector boxes, alcohol prep pads, surgical mask, face shields, gloves, and other personal protective equipment.
- C. Certificate of Product Registration (CPR) refers to a certificate issued by the FDA for products that have been approved and registered in the Philippines.
- D. Coronavirus Disease 2019 (COVID-19) refers to a disease caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).
- E. COVID-19 Vaccination Program refers to the response of the National Government in addressing the adverse impact of COVID-19 through the delivery and administration of both procured and donated COVID-19 vaccines, management of AEFIs and indemnification as covered under the Act.
- F. Emergency Use Authorization (EUA) refers to an authorization issued by the FDA for unregistered drugs and vaccines in a public health emergency. The EUA is not a CPR or a marketing authorization.

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- G. Health Technology Assessment Council (HTAC) refers to the body composed of health experts created within DOH to conduct Health Technology Assessment 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.
- H. National Immunization Technical Advisory Group (NITAG) also the interim NITAG (iNITAG) refers to the advisory body providing guidance to national policy-makers and program managers to enable them to make evidence-based immunization-related policy and program decisions.
- 1. Philippine Red Cross refers to a voluntary, independent and autonomous nongovernmental society auxiliary to the authorities of the Republic of the Philippines in the humanitarian field, as set forth in RA No. 10072, or the "Philippine Red Cross Act of 2009."
- J. Procuring Entity refers to any branch, constitutional commision, or office, agency, department, bureau, or instrumentality of the government, including, state universities and colleges, government owned and/or -controlled corporations, government financial institutions, and LGUs procuring goods, consulting services and infrastructure projects, and lease of goods and real estate, including humanitarian organizations and private entities, among others, authorized to procure COVID-19 vaccines as well as goods and services necessary for their storage, transport, deployment and administration.
- K. Serious Adverse Effects (SAE) it shall also refer to serious AEFIs. that upon causality assessment, is classified as "vaccine product-related reaction" or "vaccine quality defect-related reaction", arising from the use of COVID-19 vaccine. Serious AEFIs are:
 - (a) AEFIs that result in any of the following outcomes- death, hospitalization or prolongation of an existing hospitalization, persistent or significant disability or incapacity, and congenital anomaly or birth defect;
 - (b) AEFIs that may be severe, critical or life-threatening;
 - (c) AEFIs that require intervention to prevent any of the above-mentioned outcomes; or
 - (d) AEFIs that are classified by the Department of Health, as recommended by the National AEFI Committee (NAEFIC), as a medically important event or reaction.
- L. Third Party Logistics (TPL) refers to a third party service provider, either government or private company providing brokerage, storing/warehousing, handling and distribution services, among others, including software and tracking system for the vaccine.

VI. GENERAL GUIDELINES

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A. The COVID-19 Vaccination Program shall follow the guidelines set forth in the pertinent sections of the Act, the Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines, and all relevant existing guidelines.

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- B. The National Government, through the DOH, NTF, LGUs and other duly constituted authorities and instrumentalities, shall address the adverse impact of COVID-19 through the procurement and administration of safe and effective COVID-19 vaccines.
- C. The DOH and the NTF may enter into a multiparty agreement for the procurement of COVID-19 vaccines by LGUs and Private Sector, including goods and services necessary for their storage, transport, deployment and administration, subject to change and experimental nature of COVID-19 vaccines.
- D. Only COVID-19 vaccines with valid EUAs issued by the FDA through FDA Circular No. 2020-036 entitled, "Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID 19", and with positive recommendations from HTAC shall be procured by the DOH while an FDA-issued CPR is unavailable.
- E. Only COVID-19 vaccines procured or donated with a valid EUA issued by FDA shall be distributed and administered by the DOH, the NTF, LGUs, and other Procuring Entities including the private sector, as may be recognized in the multiparty agreement, subject to the prevailing guidelines under the COVID-19 Vaccination Program.
- F. The EUA instructions issued by the FDA shall be considered in the judicious planning and allocation tasks of the NTF Vaccine Cluster, in the distribution and program management of the regional and local Vaccine Operations Center (VOC), as well as, in the administration of COVID-19 vaccines by trained healthcare personnel.
- G. The identified Priority Eligible Groups, meriting further definition as provided in iNITAG Resolution No. 1, Series of 2021, and its succeeding amendments, shall be defined by the relevant national government agencies, such as, but not limited to, the Department of Social Welfare and Development (DSWD), Department of the Interior and Local Government (DILG), Department of Labor and Employment (DOLE), and the Department of Trade and Industry (DTI).
- H. The Philippine COVID-19 Vaccine Information Management System (VIMS) shall be the official key process automation, data management system, and data repository of the COVID-19 Vaccination Program. The DOH and DICT, together with other relevant NGAs, shall publish relevant guidelines regarding the implementation of the Philippine COVID-19 VIMS.
- 1. All vaccine recipients shall be monitored for the manifestation of any AEFI and referred to the appropriate facility for management.
- J. Minimum public health standards, including, but not limited to, physical distancing, hand hygiene, cough and sneeze etiquette, wearing of face masks, face shields, engineering, administrative, and PPE controls, among others, shall be strictly implemented during the implementation of the COVID-19 Vaccination Program.

VII. SPECIFIC GUIDELINES

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A. Procurement of COVID-19 Vaccines and Ancillary Supplies and Services

1. The DOH and the NTF, either through themselves jointly or in cooperation with any NGA or instrumentality or LGU, or private entity shall be authorized to procure COVID-19 vaccines, including goods and services necessary for

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their storage, transport, deployment, and administration through the Negotiated Procurement under Emergency Cases modality pursuant to Section 53(b) of RA No. 9184 or the "Government Procurement Reform Act" and Section 53.2 of the 2016 Revised IRR of RA No. 9184. 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. The NTF, together with the DOH, shall issue a separate guideline to operationalize the procedures in the procurement of COVID-19 vaccines for the Procuring Entities, such as the LGU and the private sector consistent with the guidelines provided in this IRR and in line with the intent of the Act to allow flexibility in the participation of all LGUs and the private sector. Such guideline shall be posted prominently in the official websites of the DOH at <u>https://doh.gov.ph/</u> and the Inter-agency Task Force for the Management of Emerging Infectious Diseases (IATF-EID) at <u>https://iatf.doh.gov.ph/</u>.
- 3. The NTF, together with the DOH, shall review the requests of LGUs to procure vaccines to ensure compliance to Section 4 of the Act, stating that LGUs shall procure no more than seventy-five percent (75%) of their target population for vaccination; Provided. That the seventy-five percent (75%) cap may be adjusted by the IATF-EID when there is sufficient supply of vaccines as determined by the DOH and the NTF.
- 4. In the procurement of COVID-19 vaccines, the DOH and the NTF, through its Task Group on Procurement and Finance, shall be authorized to negotiate, review, draft, and approve relevant legal documents (e.g. Non-Disclosure Agreement, Term Sheet, Supply Agreement) 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 parties.
- 5. Notwithstanding RA No. 7160, as amended, or the "Local Government Code of 1991," Section 88 of Presidential Decree (PD) No. 1445, as amended, or the "Government Auditing Code of the Philippines," and other applicable laws, all LGUs and other Procuring Entities authorized to procure COVID-19 vaccines may pay, remit, or transfer advance payment if required by the suppliers, manufacturer, or distributor. However, the advance payment shall be applicable only to COVID-19 vaccines and goods and services necessary for their storage, transport, deployment, and administration.
- 6. After the negotiations by the DOH and the NTF, through its Task Group on Procurement and Finance, the LGUs and other Procuring Entities shall be authorized to enter into supply agreement, advance market commitment, advance payment, research investment, purchase order, or any similar arrangements or other requirements as may be identified by the DOH and the NTF, with the pharmaceutical industry through the multiparty agreement. The DOH and the NTF shall ensure that the multiparty agreement to be signed shall contain the roles and responsibilities of all Parties involved. The NTF in coordination with the DOH shall set the parameters to be included in the legal documents in the negotiation for the vaccine purchase agreements.

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- 7. The LGUs and other Procuring Entities including the private sector shall be authorized to directly procure goods and services necessary for the storage, transport, deployment, and administration of COVID-19 vaccines, in accordance with the relevant provisions contained in the Philippine National Deployment and Vaccine Plan for COVID-19 Vaccines. The LGUs may procure through Negotiated Procurement under Emergency Cases pursuant to Section 53(b) of RA No. 9184 and Section 53.2 of the 2016 Revised IRR of RA No. 9184, and other relevant guidelines as may be issued by the GPPB.
- 8. The LGUs and other Procuring Entities, including the private sector shall ensure the delivery of their COVID-19 vaccines by contracting the services of Third Party Logistics (TPL) management providers or providing LGU-owned transportation for the delivery of the COVID-19 vaccines to the facilities of their choice, pursuant to existing relevant DOH and other government policies. In case the above mentioned conditions are inapplicable, the DOH and the concerned parties may enter into a separate agreement to ensure the delivery of vaccines.
- 9. The preceding provisions (VII.A.1-8) shall have a retroactive application from January 1, 2021.
- 10. The LGUs and other Procuring Entities including the private sector shall abide by the DOH Department Memorandum (DM) No. 2021-0116 or the "Interim Guidelines on the Identification and Utilization of COVID-19 Vaccination Sites."
- No cost of vaccination in the workplace shall be charged against or passed on, directly or indirectly, to the employees (Department of Labor and Employment Labor Advisory No. 3 s. 2021 entitled "Guidelines on the Administration of COVID – 19 Vaccines in the Workplaces.")
- 12. Non-compliance to the EUA, prioritization framework, and vaccine administration guidelines shall be used as additional consideration in future allocations and public reporting of performance, which shall be further elaborated in subsequent guidelines.
- 13. In order to preserve the efficacy of the vaccines, the DOH, NTF and their authorized representatives shall assist all LGUs and other Procuring Entities authorized to procure or accept the COVID-19 vaccines, in the conduct of pre-procurement assessment of their available cold room storage facilities, freezers, and equipment of all health facilities under their jurisdictions, and; designated recipients of the COVID-19 vaccines, as part of their readiness assessment as contained in the Vaccine Introduction Readiness Assessment Tool (VIRAT) of the WHO which is accessible through the following link: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine-introduction-RA-Tool-2020.1
- 14. In the absence of the CPR issued by FDA, manufacturers and suppliers of COVID-19 vaccines shall be prohibited to sell any COVID-19 vaccines commercially.

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B. Procurement and Administration of COVID-19 Vaccines and Ancillary Supplies and Services by LGUs

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- 1. The LGUs may procure only in cooperation with the DOH and the NTF through a multiparty agreement which shall include the DOH, NTF and the relevant suppliers of COVID-19 vaccines, through the Negotiated Procurement under Emergency Cases under Section 53.2 of the 2016 IRR of RA No. 9184, according to the pre-conditions specified therein, and other relevant guidelines as may be issued by the GPPB.
- 2. Procurement of COVID-19 vaccines by the LGUs shall not exceed seventy-five percent (75%) of their target population for vaccination, in compliance with the provision of Section VII.A.3 of this Order.
- 3. The LGUs may directly accept donations of FDA-authorized and cleared COVID-19 vaccines, subject to the guidelines and reportorial requirements of the DOH and the NTF, which give priority to the needs of the following groups: healthcare workers (HCWs), senior citizens, persons with co-morbidities, frontline personnel in essential services, and the indigent population, in the order indicated in those guidelines. LGUs shall secure the services for brokerage, handling, storage, and distribution prior to acceptance of any vaccine donation.
- 4. The LGUs and other Procuring Entities, including the private sector, in coordination with the DOH and NTF, shall have secured the services for the following: brokerage, handling, storage and distribution prior to the procurement of COVID-19 vaccines. The LGUs may procure the vaccines, through the Negotiated Procurement under Emergency Cases pursuant to the provision of the 2016 IRR of RA No. 9184, and other relevant guidelines as may be issued by the GPPB.
- 5. The preceding provisions (VII. B. 1-4) shall have a retroactive application from January 1, 2021.
- 6. For National Government-funded vaccines, the LGUs shall comply with the science and evidence-based terms and conditions of deployment while prioritizing the needs of the following groups: HCWs, senior citizens, persons with comorbidities, frontline personnel in essential services, and the indigent population.
- 7. For LGU-funded vaccines, the inoculation order shall, at all times, be science and evidence-based while prioritizing the needs of the special groups: frontline workers in health facilities, senior citizens, and indigent persons.
- 8. The local health officials of the LGU shall be allowed to formulate their own vaccine recipient list and implement their own operational procedures in accordance with the national policies and procedures issued by the DOH, such as the Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines and National Vaccine Operations Center advisories, if it will expedite and enhance the efficiency of the inoculation process and prevent the spoilage of vaccines.
- To ensure transparency, the LGUs shall also submit to the Vaccine Information Management System-Immunization Registry (VIMS-IR), a masterlist of the names and profiles of the residents, including the healthcare workers and

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uniformed personnel who were vaccinated under the COVID-19 Vaccination Program in their area, subject to the provisions of RA No. 10173 or the "Data Privacy Act of 2012", DOH DM No. 2021-0099, and further guidelines to be jointly issued by DOH and DICT, together with other relevant NGAs.

C. Procurement and Administration of COVID-19 Vaccines by Private Entities

- 1. Procurement of COVID-19 vaccines by private entities shall be in coordination and cooperation with the DOH and NTF, through its Task Group on Procurement and Finance, through the issuance of a multi-party agreement signed by the supplier/manufacturer, the private entity, and the DOH and NTF.
- 2. The procured COVID-19 vaccines shall not be for sale but for the exclusive/sole use of the private entities for workers in their businesses or for the qualified recipient entities, in case of donated COVID-19 vaccines, and that priority in the inoculation shall be their HCWs, senior citizens, economic frontliners, and essential workers.
- 3. It is only after the inoculation of these groups that they could administer the COVID-19 vaccines to their other workers qualified or assessed to be vaccinated, free of charge; Provided, That private entities may enter into arrangements with their workers to allow such workers to designate other persons as vaccine recipients subject to the EUA, the multiparty agreement and other applicable issuances.
- 4. The chief medical officers of the private entities shall be allowed to formulate their own vaccine recipient list and implement their own operational procedures, in accordance with the national policies and procedures issued by the DOH such as the National Deployment and Vaccination Plan and National Vaccine Operations Center Advisories, if it will expedite and enhance the efficiency of the inoculation process and prevent the spoilage of vaccines.
- 5. The preceding provisions (VII. C.1-4) shall have a retroactive application from November 1, 2020.
- 6. Duly accredited members and designated staff of diplomatic and consular missions and international organizations in the Philippines are included in the national vaccination program.

Accredited missions and international organizations concerned may procure vaccines or receive vaccines intended for them by their respective sending governments or organizations. Said vaccines must have an EUA from the FDA and shall only be intended for use by and administered to, duly accredited members of the diplomatic and consular missions and international organizations, as well as their staff, including local hires, and immediate family members of their household in the Philippines.

Towards this end, all accredited missions and international organizations shall submit relevant details to the DOH, through the Department of Foreign Affairs (DFA), for their integration into the national vaccination program. A report shall also be submitted to the DOH, through the DFA, regarding the number of vaccinated individuals based on the number of vaccines supplied or procured for registration in the VIMS-IR and for the requisite monitoring of AEF1s, in accordance with the system of reporting contained in the relevant provisions of the National Deployment and Vaccination Plan.

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7. International humanitarian organizations, such as the bodies under the United Nations (e.g. WHO) and the Philippine Red Cross, may procure COVID-19 vaccines, for the use of individuals consistent with the priority list set. The Philippine Red Cross shall subscribe to its advocacy for every one vaccine bought, one vaccine shall be donated to the vulnerable and indigent population. All engaged international humanitarian organizations shall report to the DOH, the number of vaccinated individuals based on the number of procured vaccines.

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- 8. To ensure transparency, the private sector shall also submit to the VIMS-IR, a masterlist of the names and profiles of their employees including the HCWs who were vaccinated through the multiparty agreement, subject to the provisions of the 2012 Data Privacy Act, DOH DM No. 2021-0099, and further guidelines to be jointly issued by DOH and DICT, and together with other relevant NGAs. The private sector shall also ensure it subscribes to the system of reporting of AEFIs as contained in relevant provisions of the National Deployment and Vaccination Plan.
- 9. The DOH, NTF, LGUs, and private entities procuring COVID-19 vaccines may coordinate with the Philippine Red Cross in the administration, distribution, and inoculation of their procured vaccines.

D. Transparency and Accountability in COVID-19 Vaccine Procurement

- 1. The National Government, LGUs, private entities, and the Philippine Red Cross shall procure vaccines that are registered with the Philippine FDA as evidenced by a valid EUA, through the multiparty agreement with DOH and NTF.
- 2. The following information shall be posted in a conspicuous place of the Procuring Entity and in the GPPB online portal within thirty (30) days after award or execution of definitive agreement or after the effectivity of this IRR, whichever is applicable, subject to the terms and conditions of the multiparty agreement entered into by involved parties.
 - a. Approved budget for the contract;
 - b. Name and details of the COVID-19 vaccines or ancillary services or supplies;
 - c. Name of the supplier, manufacturer, or distributor; and
 - d. Amount of contract as awarded.

E. Authority to Make Recommendations Based on Preliminary Data from Phase III Clinical Trials

- 1. The HTAC shall have the authority to make recommendations to the DOH on the procurement of COVID-19 vaccines based on the preliminary data from Phase III clinical trials and the WHO recommendations, in the absence of completed Phase III and Phase IV clinical trials. The assessment shall be initiated upon official request of the end-user office.
- 2. The COVID-19 vaccine shall have been issued an EUA by the FDA.
- 3. The EUA issuance by the FDA, and HTAC recommendation are two separate processes that may be done in parallel to fast-track the review and assessment of COVID-19 vaccines.

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- 4. The authority granted to the HTAC herein shall be valid for as long as the EUA issued by the FDA is in effect. In cases where the EUA is either revoked or cancelled, ongoing health technology assessment (HTA) shall be terminated and completed results are nullified.
- 5. The DOH AO 2021-0022 or the "Guidelines on the Facilitation and Management of Donations to the Health Sector During the COVID-19 Pandemic" shall be used as the guiding policy in relation to HTAC recommendations on donated vaccines.

F. Immunity from Liability

Public officials and employees, contractors, manufacturers, volunteers, and representatives of duly authorized private entities who are duly authorized to carry out and are actually carrying out the COVID-19 Vaccination Program shall be immune from suit and liability under Philippine laws with respect to all claims arising out of, related to, or resulting from the administration or use of COVID-19 vaccines under the COVID-19 Vaccination Program, except those arising from willful misconduct and gross negligence.

G. Pharmacists and Midwives as Vaccinators

- Notwithstanding the provisions of RA No. 10918 otherwise known as the "Philippine Pharmacy Act of 2016", licensed pharmacists may administer COVID-19 vaccines which are FDA-approved or which possess an EUA, provided that they undergo training on vaccine administration and AEFI management by the DOH. The COVID-19 vaccination sites shall require the training certificates of the pharmacists before they are allowed to administer COVID-19 vaccines.
- 2. Notwithstanding the provisions of RA No. 7392, or the "Philippine Midwifery Act of 1992", licensed midwives may administer COVID-19 vaccines which are FDA approved or which possess an EUA, provided they are duly trained and certified by the DOH who shall issue certificates of completion.
- 3. Standard training courses on COVID-19 vaccine administration and AEFI management shall be provided by DOH through its CHDs and partner agencies and shall be made available at no-cost to all pharmacists and midwives and other health professionals through online platforms. All DOH courses shall be accredited by the Professional Regulation Commission as Continuing Professional Development (CPD) programs.

H. COVID-19 National Vaccine Indemnity Fund

- 1. The COVID-19 National Vaccine Indemnity fund shall be administered by PhilHealth as a trust fund to compensate for any person inoculated through the COVID-19 Vaccination Program in case of death, permanent disability or hospital confinement for any SAEs.
- 2. The amount of five hundred million pesos (P500,000,000.00) sourced from the Contingent Fund, as provided under RA No. 11518 or the "General

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Appropriations Act of 2021", shall augment the funds of PhilHealth for this purpose.

- 3. Philhealth shall issue relevant implementing guidelines on the availment of indemnification for death, permanent disability or hospital confinement for any SAEs.
- 4. The indemnity fund shall be valid and available for release and disbursement until terminated by the President of the Philippines, based on the finding of the Permanent Committee. which was created under Executive Order No. 292, s. 1987, that the purpose for which the fund has been established has been fulfilled. The Permanent Committee shall also determine the amount that shall revert to the National Treasury upon its termination.
- 5. The Philhealth, in consultation with the DOH, the Department of Finance, the Department of Budget and Management and the NTF, shall issue the necessary guidelines for the planning, administration, and monitoring of the utilization of the fund, including the determination of its sufficiency.
- 6. The IATF-EID shall establish a Special Task Group composed of medical and vaccine experts with proven track record, who will be in charge of monitoring the probable adverse effects following immunization from COVID-19. The Special Task Group shall promulgate the necessary guidelines on the monitoring, evaluation, investigation, and reporting mechanism to be followed by all LGUs and private entities.
- 7. This section shall be valid and in effect for a period of five (5) years from the effectivity of the Act or until the government has declared the completion of the COVID-19 Vaccination Program, whichever comes earlier.

I. Exemption from Import Duties, Taxes and Other Fees for Procurement, Deployment, and Administration of COVID-19 Vaccines

Beginning January 1, 2021, the procurement, importation, donation, storage, transport, deployment, and administration of COVID-19 vaccines through the COVID-19 Vaccination Program by the government or any of its political subdivisions and by private entities shall be exempt from customs duties, value-added tax, excise tax, donor's tax. and other fees; Provided, That the vaccines shall not be intended for resale or other commercial use and shall be distributed without consideration from persons to be vaccinated.

J. COVID-19 Vaccine Card

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 In the implementation of the vaccination program following relevant provisions in the Philippine National Deployment and Vaccination Plan, no vaccine shall be administered to anyone who has not submitted a signed informed consent form, pursuant to existing guidelines in DOH DM No. 2021-0099 or the "Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19." A standardized COVID-19 vaccine card shall be issued to vaccine recipients to ensure completion of the required doses by documenting details of their vaccination.

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- 2. Subject to the provisions of RA 10173 or the "Data Privacy Act of 2012", the DOH shall issue vaccine cards to all persons vaccinated. To fast track the process, the DOH may delegate the processing and issuance of the vaccine cards to LGUs and private entities, subject to guidelines to be promulgated by the DOH.
- 3. The vaccine card shall contain the following information with a template to be issued by the DOH:
 - a. Basic personal information such as full name, present and/or permanent address, and birthdate;
 - b. Manufacturer, brand name, batch number, lot number, or other identifier of the COVID-19 vaccine;
 - c. Date and time of vaccination;

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- d. Name of the hospital, health center or health facility where the vaccine was administered;
- e. Name, signature, and license number of the duly licensed physician, nurse, pharmacists, midwives or other health worker administering the vaccine;
- f. Date of the last RT-PCR testing and the name of the laboratory that conducted the last RT-PCR testing, if applicable;
- g. Name and details of contact person or person to be notified, in case of emergency; and,
- h. Other information which may be determined as necessary by the Secretary of Health or the IATF-EID.
- 4. The issuance of the vaccine card is intended to be digital. The DOH, through the DICT, shall develop the LGU-based digital systems and applications that shall meet the objectives of the COVID-19 Vaccination Program while maintaining quality, safety, ease of use, and accessibility for all Filipinos.
- 5. The vaccine card shall remain accessible through other means such as printed cards. The vaccine card shall be printed by the facility/LGU in line with the printing standards/template set by the DOH.
- 6. The scheduled date for the second dose, if applicable, shall be indicated in the second dose box in the vaccine card.
- 7. The DOH shall maintain a central database of vaccinations, and mandate a uniform format for the vaccine card, the contents of which shall be updated accordingly to always conform with globally accepted standards.
- 8. The vaccine card shall not be considered as an additional mandatory requirement for educational, employment, and other similar government transaction purposes.
- 9. Individuals vaccinated against COVID-19 as indicated in the vaccine card shall not be considered immune from COVID-19, unless otherwise declared by the DOH based on reliable scientific evidence and consensus.
- 10. No fees shall be collected for the issuance, amendment or replacement of a vaccine card.
- 11. The amount needed for the initial implementation shall be charged against available funds for the purpose. Funds necessary for the continued

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implementation shall be included in the annual General Appropriations Act (GAA).

K. Reportorial Requirement and Creation of an Oversight Committee

- 1. The Vaccine Czar, the DOH, and the IATF-EID shall submit a monthly report to Congress on the implementation of the COVID-19 Vaccination Program which shall include:
 - a. Agreements made by Procuring Entities;
 - b. Date of delivery;

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- c. Vaccine storage and deployment;
- d. Number of persons vaccinated; and,
- e. Other relevant information as may be required.
- 2. The DOH shall develop the template, indicators, and process of submission of reports to the Congress, which will be issued in separate guidelines.

VIII. RESPONSIBILITIES OF NGAS, NTF, LGUS AND PRIVATE ENTITIES

- A. The NTF together with the DOH shall develop supplemental operational guidelines on the procurement of COVID-19 Vaccines for reference of Procuring Entities such as the LGUs and the private sector, as may be needed consistent with the guidelines provided in this IRR and in line with the intent of the Act to allow flexibility in the participation of all LGUs and the private sector.
- B. PhilHealth shall issue the implementing guidelines covering Section 10 of the Act on COVID-19 National Vaccine Indemnity Fund to compensate persons encountering SAEs and other provisions as stated in the section.
- C. Cascading of policies related to the COVID-19 Vaccination Program shall be facilitated by the NTF, DOH, Department of the Interior and the Local Government (DILG), Philippine Information Agency (PIA), and other concerned member agencies of the NTF to ensure that vaccination plans of LGUs and other private entities are in line with the overall vaccination plan of the National Government.
- D. The DOH, NTF, LGUs and private entities may partner and coordinate with the Philippine Red Cross in the administration, distribution, and inoculation of COVID-19 vaccines.
- E. The GPPB shall issue the guidelines, as may be necessary, on the procurement process and transparency requirements under Section 6 of RA No. 11525.

IX. PENAL PROVISION

Falsification of a vaccine card shall be punishable under Act No. 3815 as amended, or "The Revised Penal Code."

Sale, advertisement, procurement, distribution or administration of COVID-19 vaccines without a valid EUA issued, shall be penalized based on the appropriate provisions of RA No. 9711, or the "Food and Drug Administration Act of 2009," and other relevant existing rules, regulations and issuances.

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X. SEPARABILITY CLAUSE

If any part, section or provision of this IRR is held invalid or unconstitutional, the remaining parts or provisions not affected thereby shall remain in full force and effect.

XI. REPEALING CLAUSE

All orders, rules, regulations, and other related issuances inconsistent with or contrary to this IRR are hereby repealed, amended, or modified accordingly. All other provisions of existing issuances which are not affected by this Order shall remain valid and in effect.

XII. EFFECTIVITY

This Order shall take effect immediately after its publication in the Official Gazette or in any national newspaper of general circulation, with three (3) certified copies to be filed with the Office of the National Administrative Register (ONAR) of the University of the Philippines Law Center. This shall remain in full force during the period of state of calamity as declared under Proclamation No. 929, which was extended by Proclamation No. 1021, unless otherwise rescinded or revised.

FRANCISCO T. DUQUE III, MSc SEC Department of Health

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SEC. CARLITO G. GALVEZ, JR. Vaccine Czar, National Task Force Against COVID-19