



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

November 6, 2014

No. 2014 - 0023

SUBJECT: Designation of the Research Institute for Tropical Medicine [RITM] as the Philippine National Influenza Center (PNIC)

I. RATIONALE/BACKGROUND

Influenza is a recurring respiratory condition recognized as occurring particularly during the winter months in temperate countries where influenza was first observed. Influenza has high morbidity rates for children and for adults about 60 years old, patients with chronic illness and pregnant women. The influenza virus A that affects humans mutates easily, often causing new antigenic variants, and the occurrence of influenza pandemic. The 1957—1958 Asian influenza was caused by Influenza A/H2N2, while the Hong Kong flu which took place in 1968-1969, resulting in nearly one million deaths, was caused by Influenza A/H3N2. The SARS outbreak in 2004 also demonstrated the speed by which new and emerging infections may be transmitted. The occurrence of a potential influenza pandemic is unpredictable, imminent and possibly inevitable. In 2009 the world, experienced the 2009 Influenza A/H1N1 pandemic resulting in 18,000 deaths according to the World Health Organization (WHO).

The Philippines Disease Integrated Surveillance and Response (PIDSR) is a multifaceted public health disease surveillance system that provides public health officials the capabilities to monitor the occurrence and spread of diseases. The goal of the PIDSR is to strengthen surveillance and response capabilities at each level of the health system by building local capacities and leveraging strengths and areas of expertise through partnership and coordination. The vision of PIDSR is to improve the availability and use of surveillance and laboratory data so that public health managers and decision makers can plan for and carry out more timely detection and response to the leading causes of illness, death and disability. Information from the PIDSR is expected to be used for the following purposes:

- Facilitate collecting, managing, analyzing, interpreting, and disseminating health related data for diseases designated as nationally notifiable,
- Develop and maintain national standards, such as consistent case definitions for nationally notifiable diseases) applicable across all the provinces and cities,
- Maintain the official national notifiable diseases statistics
- Provide detailed data to control programs to facilitate the identification of specific disease trends;

and

-Work with cities and provinces and partners to implement and assess prevention and control programs.

Influenza-Like-Illness (ILI) is among the notifiable diseases under the PIDSR. In addition to obtaining epidemiologic information, it also collects data on whether laboratory confirmation was done of the ILI case either through virus isolation or polymerase chain reaction (PCR). It also classified ILI cases as either suspect or laboratory confirmed, thereby highlighting the role of laboratory procedures as necessary in the classification of ILI cases.

The Global Influenza Surveillance and Response System (GISRS)¹, previously known as the Global Influenza Surveillance Network (GISN), has set up a network for the conduct of influenza virological surveillance since 1948. An integral part of GISRS activities is the laboratory diagnosis and virological surveillance of circulating influenza viruses — key elements in both influenza vaccine virus selection and the early detection of emerging viruses with pandemic potential. The primary aims of the system have been threefold: to monitor changes in antigenicity of influenza viruses; to guide the selection of strains for the annual influenza vaccine; and to provide virus samples for use in vaccine production. The GISRS consists of over 130 National Influenza Centres (NICs) around the world that collect and test clinical specimens, submitting a sample of these to WHO Collaborating Centres (WHO CC) and Essential Regulatory Laboratories for further characterization.² In effect that GISRS has contributed significantly to the protection of global public health by updating seasonal influenza vaccine compositions and by functioning as a global alert mechanism for the emergence of influenza viruses with pandemic potential.

The Research Institute for Tropical Medicine participated in the GISN as the country's sole National Influenza Center in 2005. The WHO recognized the RITM insofar as influenza surveillance information is concerned and has participated in all the NIC related activities as called for by both the WHO and the US-CDC. This was further facilitated by a grant provided by the US —Centers for Disease Prevention and Control (CDC) that RITM and the Department of Health's National Epidemiology Center (NBC) to develop a national influenza surveillance for the country from 2005 to 2010. Because of an oversight, the RITM was not designated the country's NIC by its national authorities, in this case, the Department of Health, although it has functioned as such for nearly a decade now. It is about time for the RITM to be officially designated as the Philippines' National Influenza Center.

II. DECLARATION OF POLICIES

The creation and organization of the PNIC shall be guided by the following legal mandates and policies:

A. Republic Act 3573 (Law of Reporting of Communicable Diseases) requires all individuals and health facilities to report notifiable disease to local and national health authorities. Influenza is

among the notifiable disease of the DOH through the NEC.

1 GISRS is the new name adopted by the World Health Assembly in resolution 64.5, replacing the former name of the Global Influenza

Surveillance Network (GISN) 2 For the current list of National Influenza Centres,
<http://www.who.int/csr/disease/influenza/centres/en>

3 For the current list of influenza Collaborating Centres and Essential Regulatory Laboratories see
<http://www.who.int/csr/disease/influenza/centres/en>

B. Resolution WHA 48.13 (1995) urges all Member States to strengthen national and local programs of active surveillance for infectious disease, ensuring that efforts are directed towards the early detection of epidemics and prompt identification of new emerging and re-emerging infectious diseases.

C. Resolution WHA 58.3 (2005) urges all Member States to develop, strengthen and maintain, as soon as possible, but not later than five years from the entry into force of the revised International Health Regulations (IHR), the capacity to detect, assess, notify and report events in accordance with these regulations.

D. Resolution WHA585 (2005) urges all Member States to develop and strengthen national surveillance and laboratory capacity for human influenzas.

E. Resolution WHA59.2 (2006) urges all Members States the mobilization of financial support, in building, strengthening and maintaining the capacity for influenza surveillance and response in countries affected by avian influenza or pandemic influenza;

F. Resolution WHA 64.5 (2011) urges all member states particularly developing countries to develop national laboratory and influenza surveillance capacity including: the early detection, isolation and characterization of viruses, participate in pandemic risk assessment and response, develop research capacity related to influenza and achieve technical qualifications for consideration of laboratories as National Influenza Centers;

G. Administrative Order No 2005—0023 (Implementing Guidelines for Formula One for Health as Framework for Health Reforms) Section C2 states that 'Disease surveillance shall be intensified to ensure that the targets for disease elimination prevention and control are attained. '

H. Department Personnel Order No. 2005 — 1585 (Creation of Management Committee on Prevention and Control of Emerging and Re—emerging Infectious Diseases (DOHMC—PCREID) creates the Epidemiology and Surveillance Sub- Committee (ESSC) in which one of its major functions is to '...formulate and recommend policies, standards, procedures guidelines and systems on the early detection, contact tracing, surveillance , investigation and follow-up of emerging and re-emerging (EREID) suspects and the timely and accurate recording, reporting and collation of

epidemiological data on EREID."

I. Administrative Order No 2007-0036 (Guidelines on the Philippine Integrated Disease Surveillance and Response (PIDSR) Framework. This administrative order provides the framework for the PIDSR to guide its implementation at all levels of the health care delivery system as well as both the public and private

III. GOALS AND OBJECTIVES

A. The designation of a functional, integrated and sustained National Influenza Center resulting in the appropriate response during influenza pandemics and policy recommendations for influenza prevention and control.

B. General Objective

1. To develop, improve/ strengthen and sustain influenza laboratory surveillance in the country.
2. To provide continuous, timely and accurate influenza laboratory surveillance information to guide influenza pandemic response or interventions for all stakeholders from the national to the local levels.

C. Specific Objectives

1. To designate the Research Institute for Tropical Medicine as the Philippine National Influenza Center.
2. To define the terms of reference, duties and responsibilities of the PNIC.
3. To provide guidelines for the establishment, organization, operationalization and sustainability of the PNIC.
4. To provide the mechanism by which the PNIC support influenza disease surveillance by the NBC and response by the National Center for Disease Prevention and Control 4 Infectious Disease Office (NCDPC — IDO),

during the inter-pandemic period and during pandemic periods.
5. To define the terms of reference, duties, responsibilities and operations of the Influenza Sub—National Laboratories.

IV. SCOPE AND COVERAGE

This Administrative Order covers the designation of the RITM as the Philippine National Influenza

Center (PNIC) its terms of reference, tasks and responsibilities and the provisions required for its continued operations and sustainability. It also covers the creation and terms of reference of the Influenza Sub-National Laboratories.

The guidelines and standards prescribed thereto shall be applied to, and benefit, the entire health sector, with the Dept. of Health as the lead agency.

V. DEFINITION OF TERMS

Disease surveillance

The systematic, continuing assessment of the health of a community, based on the collection, interpretation and use of health data. Surveillance provides information necessary for public health decision-making.

Influenza epidemic

An outbreak of influenza caused by influenza A or B viruses that have undergone antigenic drift. The terms "influenza epidemic" and "influenza outbrea " have the same meaning, and may occur locally or in many parts of the world during the same season.

Influenza pandemic

By convention, worldwide outbreaks of influenza caused by influenza A viruses that have undergone antigenic shift. A pandemic is a global disease outbreak. A flu pandemic occurs when a new influenza virus emerges for which people have little or no immunity and for which there is no vaccine. The disease spreads easily person-to-person, causes serious illness, and can sweep across the country and around the world in very short time.

Influenza Inter-Pandemic Period

The influenza inter-pandemic period has two phases. In Phase 1 no new influenza virus subtypes have been detected in humans; the influenza virus subtype that has caused human infection may be present in animals, but the risk of human infection or disease is considered to be low. In Phase 2, although no new influenza virus subtypes have been detected in humans, there is a circulating animal influenza virus subtype posing a substantial risk of human disease.

National Influenza Centers

Are institutions recognized by the World Health Organization to perform influenza virological surveillance. These NICs collect specimens in their country, perform primary virus isolation and preliminary antigenic characterization. They also ship newly isolated strains to WHO Collaborating Center for high level antigenic and genetic analysis, the result of which forms the basis for WHO

recommendations on the composition of influenza vaccine for the Northern and Southern Hemisphere each year.

Influenza Virological surveillance

The influenza inter-pandemic period has two phases. In Phase 1 no new influenza virus subtypes have been detected in humans; the influenza virus subtype that has caused human infection may be present in animals, but the risk of human infection or disease is considered to be low. In Phase 2, although no new influenza virus subtypes have been detected in humans, there is a circulating animal influenza virus subtype posing a substantial risk of human disease.

Polymerase Chain Reaction

A powerful, molecular technique for the identification of influenza virus genomes even when they are present at very low levels.

The ongoing and systematic collection and analysis of influenza viruses in order to monitor their characteristics.

VI. GENERAL PROVISIONS

The International Health Regulations of 2005 aims to protect countries against international disease spread while avoiding unnecessary interference with global travel and trade. Succeeding resolutions of the World Health Assembly from 2005 to 2011, highlighted the urgency and the significance of developing national laboratory and influenza surveillance capacity including the mobilization of financial support for strengthening and sustaining this laboratory capacity. As a member state of the World Health Assembly, the Philippines has the obligation to prevent and control the spread of disease inside and outside its borders,

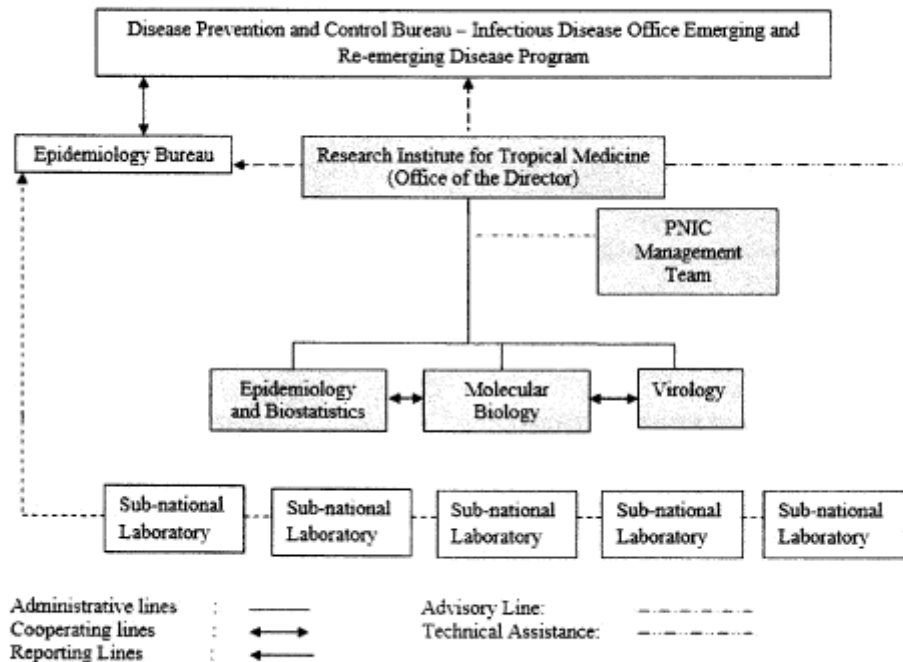
specially for diseases like influenza which is both an emerging and re-emerging disease.

In recognition of this, the Department of Health hereby orders that the Research Institute for Tropical Medicine is the country's National Influenza Center and shall receive

the technical, logistic and financial support to perform its functions.

VII. GUIDELINES FOR THE OPERATIONS OF THE PNIC

1. Organizational Structure of the NIC



Disease Prevention and Control Bureau — Infectious Diseases for Prevention and Control Division (DPCB-IDPCD). This office is primarily responsible for the development and implementation of the integrated national preparedness and response plan, to provide updates, technical advice and recommendations on the recognition, prevention and control of diseases and the organization of the DOH Management Committee for the Prevention and Control of Emerging and Re-emerging Infectious Diseases, to provide logistical support for surveillance and laboratory activities. EB shall share with the DPCB the report on influenza laboratory confirmed cases.

Epidemiology Bureau (EB). This office is primarily responsible for collection of information on notifiable diseases through the PIDSR and detecting or confirming disease outbreaks. Through its sentinel sites, it will refer ILI from its sentinel sites to the PNIC for influenza laboratory testing. Since ILI is among the notifiable diseases for which information is required to classify an ILI case as suspected or laboratory confirmed, the PNIC will report to the EB all the laboratory results of ILI cases from whom nasal swabs are obtained. It is also responsible for providing logistical support for surveillance activities which includes laboratory confirmation.

Philippine National Influenza Center (PNIC). Within the RITM, the PNIC is composed of three departments: Virology, Molecular Biology and Epidemiology and Biostatistics. The functions of these departments are as follows:

Department of Virology (DV). This department is responsible for the detection of influenza and other viruses using Polymerase Chain Reaction (PCR) and viral isolation techniques. This will

require the laboratory to maintain several cell lines to allow for the detection of a variety of respiratory pathogens, in addition to influenza. The DV is also responsible for the typing, subtyping and further determining the antigenic characteristics of influenza viral isolates using the haemagglutination inhibition (HA1) test. In instances when isolates need confirmation or are unsubtypeable, the department will send these isolates to a WHO Collaborating Center. The department is also responsible for the training of health workers in the collection, storage and transport of specimen in different sentinel sites.

Molecular Biology Department (MBL). This department is responsible for the application of molecular techniques to directly detect influenza A or B genetic material in respiratory samples or viral cultures. The employment of these techniques can greatly facilitate the identification of human influenza A subtypes including those with the potential to cause a pandemic and thus expedite the investigation of outbreaks of respiratory illness. It is the primary department responsible for processing of specimen during influenza pandemic and the training of sub—national laboratories staff in the use of conventional and real-time PCR for influenza detection.

Department of Epidemiology and Biostatistics (DEBS). This department is responsible for the data management of the data collected and generated by the PNIC. It is also responsible for the provision of information on influenza activity in the country to the Epidemiology Bureau (EB) of the Department of Health and World Health Organization through the FLUNET.

Office of the Director of the RITM is at the same time the Director of the PNIC, who has administrative responsibilities over the departments under the NIC. Its operations are overseen by the Center Management Team (CMT) which is composed of the departments under the PNIC, including the Institute's Chief Administrative Officer and head of the Accounting Departments.

Sub-national Laboratories. These are laboratories housed in regional hospitals and equipped with the facility required to perform real time PCR procedures on influenza samples collected.

2. Functions of the PNIC

2.1. General Functions of the PNIC

2.1.1. Provides laboratory support for the ILI and SARI surveillance of the EB, as part of its Philippines Integrated Disease Surveillance and Response (PIDS), through the laboratory diagnosis of influenza using viral isolation and/or molecular techniques.

2.1.2. Continuously strengthen the PNIC capacity to support ILI and SARI surveillance, influenza outbreaks and pandemic through (1) the recruitment, hiring and training of adequate personnel, (2) acquisition of appropriate equipment, (3) participation in regular influenza conferences, meetings and training activities conducted by WHO, CDC and other relevant authorities and (4) participation in the WHO influenza quality assurance activities.

2.1.3. Makes recommendations for the setting up of additional sub-national laboratories or in the

upgrade of laboratory equipment in these laboratories, if necessary.

2.1.4. Trains staff of the sub-national laboratories in the timely and accurate detection of pandemic influenza viruses using appropriate molecular techniques, i.e. Real Time PCR.

2.1.5. Provides proficiency and external quality assessment for the sub— national laboratories in the detection of influenza virus types by PCR to monitor the quality of its diagnoses and identify gaps of PCR testing in these laboratories.

2.1.6. Provides technical assistance in the conduct of SARI surveillance in the hospitals housing sub-national laboratories.

2.1.7. Acts as the national reference laboratory for influenza.

2.1.8. Serves as the resource for training on influenza surveillance of the Department of Health.

2.1.9. Serves as the key point of contact with the DOH Epidemiology Bureau and the World Health Organization in all concerns and questions relating to influenza virological surveillance.

2.1.10. Maintains active communication with. the EB and the members of the WHO - GISN through (1) the timely submission of virus isolates to the WHO Collaborating Centers, (2) prompt information on isolation of unusual viruses or disease outbreaks, (3) weekly reports on influenza activity during the influenza season and the provision of any other relevant information on influenza surveillance and control to FLUNET and other health authorities.

2.2. Specific Functions of the PNIC

During the Interpandemic Period

2.2.1. Provides laboratory support for the routine ILI and SARI epidemiologic surveillance conducted by the EB as part of its Philippines Integrated Disease Surveillance and Response (PIDSRS).

2.2.2. Processes collected clinical specimen from (1) routine ILI and SARI surveillance and (2) during influenza outbreaks for the detection and/ or isolation of influenza virus.

2.2.3. Provides guidance and training in the biosafety requirements for influenza diagnosis _ including the safe handling, storage and transport of specimen.

2.2.4. Conducts seasonal influenza virus isolation and preliminary analyses of the virus isolates and send representative isolates to the WHO — Collaborating Center.

2.2.5. Monitors continuously the influenza circulating strains in the country and remains alert to non-subtypeable or low—reacting virus isolates.

2.2.6. Acts as collection point for virus isolates from sub-national laboratories, where available.

2.2.7. Participates in the pandemic planning of the Department of Health.

2.2.8. Provides regular guidance and training to the sub-national laboratories involved in influenza surveillance and diagnosis to ensure that basic PCR skills are maintained.

2.2.9. Provides regular quality assurance processes on the sub-national laboratories in the detection of influenza virus types by PCR.

2.2.10. Develops surge capacity plans in response to possible needs during the pandemic. -

2.2.11. Transport representative seasonal influenza virus isolates to WHO Collaborating Centers to contribute to the annual WHO annual recommendations on seasonal influenza vaccine composition.

2.2.12. Provides weekly report on circulating virus strains in the country to the EB and the WHO FLUNET.

2.2.13. Alerts the EB and the WHO-GISN of the :

a. Emergence of unusual outbreaks of influenza—like-illness (ILI) or severe acute respiratory illnesses (SARI);

b. Indications of the emergence of influenza viruses with pandemic potential.

2.2.14. Forwards representative virus isolates and any low reacting viruses to a WHO Collaborating Center for confirmation and further characterization.

During the Pandemic Period

2.2.15. Ensures that it is fully equipped with the necessary materials and reagents to detect new subtypes of influenza infection in humans as early as possible.

2.2.16. Provides the national authorities with the necessary virological

information for the necessary development, amendment and implementation of the national preparedness plan. . 9

2.2.17. Provides sub—national laboratories with the necessary reagents and training required to detect the new subtypes of influenza infection.

2.2.18. Ensures the prompt and timely reporting of laboratory results of cases to the referring

facilities, EB and the WHO-GISN.

2.2.19. Provide laboratory diagnosis for monitoring the geographical spread of the pandemic in the country to the EB.

2.2.20. Performs viral susceptibility testing on the pandemic virus.

2.2.21. Confirms detection of new virus for those which may not be detected by the sub-national laboratories.

2.2.22. Maintains enhanced virological surveillance for the early detection of a possible subsequent rise in pandemic influenza activity.

2.2.23. Where possible conduct serological studies to understand the spread and other features of the pandemic.

2.2.24 Coordinates closely with the Dept. of Health Central Office for the planning, response, and reporting requirements of a pandemic.

3. Functions of the Sub-National Laboratories The subnational laboratories are responsible for:

3.1. During the Intermgndernic Period

3.1.1. Provide laboratory support for the routine ILI and SARI epidemiologic surveillance conducted by the EB as part of its Philippines Integrated Disease Surveillance and Response (PIDSR) System.

3.1.2. Process collected clinical specimen from routine SARI surveillance conducted in its hospital and other hospitals in its catchment area.

3.1.3. Participate in the quality assessment procedures of the PNIC by sending representative isolates for confirmation or further characterization.

3.1.4. Monitor continuously the influenza circulating strains in the hospitals or regions and remain alert to non-subtypeable or low-reacting virus isolates.

3.1.5. Participate in the pandemic planning of the provincial and regional health offices and local government units.

3.1.6. Develop surge capacity plans in response to possible needs during the pandemic.

3.1.7. Provide weekly report on influenza. virus strains in the hospital or the region to the Regional Epidemiologic Surveillance Unit (RESU), PNIC and EB.

3.2. During the Pandemic Period

3.2.1. Process collected clinical specimen from suspected pandemic cases from the sub-national laboratory's catchment area.

3.2.2. Ensure that it is fully equipped with the necessary materials and reagents to detect new subtypes of influenza infection in humans as early as possible.

3.2.3. Provide the PNIC with the necessary virological information for the necessary development, amendment and implementation of the

national preparedness plan.

3.2.4. Ensure the prompt and timely reporting of laboratory results of cases to the referring facilities, local government units, RESU, PNIC and EB. 3.2.5. Provide laboratory diagnosis for monitoring the geographical spread of

the pandemic in its catchment area, province or region.

3.2.6. Maintain enhanced virological surveillance for the early detection of a possible subsequent rise in pandemic influenza activity.

3.2.7. Where possible conduct serological studies to understand the spread and other features of the pandemic.

3.3 Sentinel-Site Hospitals (Where Sigh-National Laboratories are Located)

3.3.1. Appoint or designate disease surveillance coordinator, preferably the Infectious Disease Physician in the hospital to be responsible for the conduct of Severe Acute Respiratory Infections (SARI) surveillance in the hospital.

3.3.2. Train physicians and nurses at the Emergency Room and in the wards in the conduct of Severe Acute Respiratory Infections (SARI) surveillance using the Interim Guidelines No. 1 On the Surveillance of

Severe Acute Respiratory Infection (SARI).

3.3.3. Request technical assistance from the Epidemiology Bureau or from the RITM in the training of hospital staff for SARI surveillance.

3.3.4. Ensure that core surveillance procedures in the conduct of SARI surveillance, including the specimen collection, are complied with.

3.3.5. Ensure that all SARI specimen are processed by the sub-national laboratory housed in the hospital and reporting procedures observed and adhered to.

3.3.6. Ensure that preliminary investigation of SARI cases seen at the hospital are investigated, as prescribed by the PID SR guidelines.

4. Logistical and Funding Support

The operations of the Philippine National Influenza Center is among the Philippine government's responsibility as signatory to the H—IR 2005. Thus, it is important that logistic support for its continued development, improvement, strengthening and sustainability be provided by the Philippines government through the Department of Health and its agencies.

4.1. The budget required for the operation, continued improvement, strengthening and sustainability of the PNIC shall be from the Office of the Secretary of the Department of Health.

4.2. The PNIC and the different sub-national laboratories shall include in its annual line item budget the amounts necessary for its continued strengthening and sustainability operations. This shall include (1) wages, benefits and other personnel expenses of the laboratory, data management, and field surveillance staff, (2) the cost of laboratory supplies and reagents, (3) participation in influenza related meetings and training, (4) participation in proficiency testing and quality assurance assessment both local and international and (5) transport of representative isolates to the NIC or to the WHO Collaborating Center.

4.3. Supplemental budgetary requests may also be submitted for funding to the DOH Epidemiology Bureau, specifically but not limited to salary augmentation, cost of reagents, utilities in case of outbreaks, epidemics and pandemics, and participation in. proficiency testing and quality assurance testing.

4.4. Supplemental budgetary request may also be submitted for finding to the Disease Prevention and Control Bureau, specifically but not limited to participation in influenza-related training and conferences.

4.5. Equipment acquisition and upgrade of the PNIC and the sub—national laboratories, including the provision of training for the operation of new equipment shall be provided through the Health Facilities and Development Bureau; any capital outlay funds available for laboratory equipment and/or disease control subject to the approval of the Secretary of Health.

VIII. REPEALING CLAUSE

All other issuances inconsistent with the provisions of this Order are hereby repealed/rescinded and modified accordingly.

1X. SEPARABILILY CLAUSE

If for any reason, any part or provision of this Order be declared invalid or unconstitutional, such shall not affect the other provisions which shall remain in full force and effect.

X. EFFECTIVITY DATE

This Order shall take effect 15 days upon approval.

ENRIQUE T. ONA, MD
Secretary of Health