[DOH ADMINISTRATIVE ORDER NO. 2010-0017, June 18, 2010]

GUIDELINES IN SURVEILLANCE AND RESPONSE TO ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

I. BACKGROUND/RATIONALE

The goal of immunization is to protect the individual and the public from vaccine-preventable diseases. Although modern vaccines are safe, no vaccine is entirely without risk. Some people experience events after immunization ranging from mild side effects to rare life-threatening, illnesses. In some cases, these reactions are caused by the vaccine; in others, they are caused by an error in the administration of the vaccine; and in the majority of cases, there is no relationship.

While most adverse events following immunization (AEFI) are mild and have no long-term consequences, serious adverse reaction can occur albeit, very rarely. Ultimately, any question from the public about the safety of vaccination is a cause for concern. They must be swiftly and effectively investigated and acted upon. Rumors and misinformation about vaccines and immunization sometimes occur because perceived or true adverse events following immunization are handled inappropriately. Incorrect information during media coverage on vaccine safety issues can further propagate and sensationalize misinformation. As a result, rumors about vaccines may spread, and lead to reduced immunization coverage and increased childhood illnesses and unnecessary deaths.

It is in this context that surveillance and management of AEFIs should be strengthened at all levels of the health system. Currently, AEFI is one of the immediately notifiable diseases/syndromes or events under the Philippine Integrated Disease Surveillance and Response (PIDSR) system of the Department of Health. However, the system provides only the reporting mechanisms of AEFIs with no provisions for the investigation and management of AEFIs. In October 2007, the DOH issued an Administrative Order (A.O. No. 2007-0028) for the implementation of *"Bakuna ang Una sa Sanggol at Ina"* that provides guidelines on reporting, treatment of AEFIs and legal assistance for health workers. The A.O. however, did not cover provisions on risk communications, organizational framework, causality assessment, laboratory investigation and other important aspects of surveillance and management of AEFIs.

It is in light of the above that a comprehensive and integrated set of guidelines for surveillance and response to AEFIs is hereby issued.

II. DECLARATION OF POLICIES

Surveillance and management of AEFIs shall be guided by the following legal mandates and policies:

Administrative Order No. 2007-0036, Guidelines on the Philippine Integrated Disease Surveillance and Response (PIDSR) Framework, Implementing Guidelines, Section A, includes AEFIs as one of the immediately notifiable diseases/syndromes or event under the Philippine Integrated Disease Surveillance and Response (PIDSR) system.

Administrative Order No. 2007-0028, Implementing Guidelines of the Executive Order No. 663" "Implementing the National Commitment for Bakuna ang Una sa Sanggol at Ina," attaining World Health Organization's goal to eliminate measles and Neonatal Tetanus, eradicate polio, control hepatitis B and other vaccine preventable diseases for the "Knock-out Tigdas", General Guidelines, provides mechanisms for reporting, treatment of AEFIs and legal assistance for health workers.

Administrative Order 0023 series of 2008 – National Policy on Patient Safety – which calls for the prevention of harm to patients thru the prevention, avoidance and amelioration of risk, adverse outcomes or injuries stemming from the process of health care.

III. SCOPE AND COVERAGE

This issuance shall apply to health professionals from the public and private sectors who are providing vaccination nationwide, the Department of Health (DOH) concerned offices and attached agencies, epidemiology and surveillance units, private and government health facilities, local government units and the community involved in the surveillance and management of AEFIs. It shall cover all vaccines administered under the Expanded Program on Immunization (EPI) program and other vaccines given by DOH.

IV. OBJECTIVES

This Order aims to guide the concerned stakeholders on the early detection and appropriate and quick response to adverse events following immunization.

V. DEFINITION OF TERMS

1. **Adverse event following immunization (AEFI)** – A medical incident that takes place after an immunization, causes concern, and is believed to be caused by immunization.

2. **AEFI Table** – A list of AEFIs or conditions and the time frames in which they must occur after vaccine administration. It is used as a tool for "presumption of causation" for all vaccines.

3. **Causation-in-fact** – Standard of proof which relies on a factual determination that a vaccine actually caused an injury or death.

4. **Cluster** –Two or more cases of the same or similar event related in time, geography, and/or vaccine administered.

5. **Coincidental adverse event** – A medical event that would have occurred whether or not the individual had received an immunization prior to the event.

6. **Disease Reporting Unit (DRU)** – Refers to any health facility where cases of notifiable diseases are identified and reported (e.g. hospitals, clinics, municipal

health offices, city health offices, barangay health stations, community, and quarantine stations).

7. **Disease Surveillance Coordinator (DSC)** – Refers to staff of government and non-government health facilities (e.g. hospitals, clinics, RHUs) who have received training on PIDSR with an official designation as disease surveillance coordinator by the head of the facility.

8. **Immunization Safety** – The public health practices and policies dealing with the various aspects of the correct administration of vaccines, focusing on minimizing the risk of transmission of disease with the injection and maximizing the effectiveness of the vaccine. The term encompasses the spectrum of events from proper manufacture to correct administration.

9. **Immunization safety surveillance** – A system for ensuring immunization safety through detecting, reporting, investigating, and responding to AEFIs.

10. **Injection Reaction** – Event from anxiety about vaccination, or pain from the injection itself rather than the vaccine.

11. **Minor AEFIs** – These are AEFIs that are not included or categorized as serious AEFIs.

12. **Pharmacovigilance** – The science and activities relating to the detection, assessment, understanding and prevention of adverse events and other possible drug-related problems.

13. **Program-related AEFI or program error** – A medical incident that was caused by some error in the transportation, storage, handling, or administration of vaccine.

14. **Safe injection practice** – Those public health practices and policies which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.

15. **Serious AEFIs** – These are AEFIs that are life threatening and those that result in hospitalization (or prolonged hospitalization), disability (or have the potential to result in disability) or death.

16. **Vaccine reaction** – An event caused or precipitated by the active component or one of the other components of the vaccine. This is due to the inherent properties of the vaccine.

VI. GUIDING PRINCIPLES

1. Vaccines used in national immunization programs are safe and effective. However, adverse events can occur following immunization. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events.

2. Surveillance of AEFIs is an effective means of monitoring immunization safety and contributes to the credibility of the immunization program. It shall allow proper management of AEFIs and avoid inappropriate responses to reports of AEFIs that can create a sense of crisis in the absence of such surveillance.

3. AEFI surveillance shall follow the basic principles for surveillance as stipulated in the implementing guidelines of the Philippine Integrated Surveillance and Response

(PIDSR) system. See AO 2007-0036.

4. AEFI reporting shall be encouraged at all levels. The aim is for early detection of AEFI so that appropriate measures can be instituted.

5. Rapid response to public concern about vaccines, as well as immediate and clear communication of explanations and actions, will preserve the integrity of the immunization program.

VII. IMPLEMENTING GUIDELINES

1. Surveillance

1.1 Detection

1.1.1 *Reportable AEFIs*

All serious AEFIs or unusual events believed to be caused by immunization shall be reported to the Immunization Safety Board (ISB) thru the National Epidemiology Center (NEC) as secretariat. Minor AEFIs shall be documented and reported to the Rural Health Unit (RHU) using the AEFI form. However, clustering of these cases shall be reported to the ISB. (Annex 1*: List of Serious AEFIs).

1.1.2 Responsibility of Reporting

The following are responsible for the detection and/or reporting of AEFIs:

a. All health workers in the government and private sectors providing immunization services and clinical treatment of AEFIs.

b. Individuals who received the vaccination can report AEFIs to any Health authority. In cases of minors, parents or guardians can report the same.

c. Researchers and research laboratories involved in clinical studies or field trials that result to AEFIs.

d. Vaccine manufacturers or distributors should also report AEFIs.

1.2 Timing and Flow of Reporting

All serious AEFIs, deaths, and unusual events shall be reported to the NEC within 24 hours. The report shall be made promptly so that immediate decision on the needed for action and investigation can be made. Initial report shall contain basic information (e.g., name, age, sex, address, onset of illness, vaccine administered and outcome of patient) and shall be transmitted through the fastest means of communication at these contact numbers: 743-8301 loc. 1905-1906, fax: loc. 1903, e-mail address: episo_doh@ yahoo.com.

1.3 Investigation

1.3.1 Purpose

a. to validate the existence of the event
b. to establish the causality of the reported event

1.3.2 Causality Assessment

a. Preliminary investigation shall be made by the Disease Surveillance Coordinators in all private and public health facilities using a PIDSR AEFI Case investigation form as soon as possible within 48 hours.

b. All Serious AEFIs (Annex 1: List of Serious AEFIs) or clusters shall be thoroughly investigated by the AEFI team at the next higher level.

c. The Regional AEFI Committee (RAEFIC) shall conduct immediate preliminary causality assessment upon receipt of the complete AEFI case investigation reports from the field.

d. The final causality assessment of Serious AEFIs shall be conducted by the Immunization Safety Board (ISB).

e. Assessment should be completed within 48 hours after each investigation.

1.4 Data Management

1.4.1 Data management (collection, consolidation, analysis and interpretation) shall be done in all Epidemiology and Surveillance Units (ESUs) using PIDSR protocols. Data shall be shared with the Food and Drug Administration.

1.4.2 The PIDSR system shall be utilized to maintain a database (paper-based or electronic) of AEFIs that is easily accessible to all reporting units.

1.5 Feedback

1.5.1 The investigating teams from all levels shall provide feedback

1.5.2 The Immunization Safety Board shall immediately give feedback to NIC and the Secretary of Health with final recommendations.

2. Response

2.1 Case Management

2.1.1 If the AEFI is due to vaccine reaction, the FDA shall issue the necessary order within 24 hours after due process, to temporarily withdraw the implicated vaccine lot/batch from