



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

NOV 19 2014

ADMINISTRATIVE ORDER
NO. 2014- 0045

SUBJECT: Guidelines on the Implementation of the Expanded Newborn Screening Program

I. Rationale

Efforts are continuously being done to achieve the goal of saving Filipino newborns for common life-threatening heritable disorders. To this end, the National Comprehensive Newborn Screening System is expanding the screening panel of disorders from six (6) to more than twenty (20) disorders. An expanded screening program will give opportunities to significantly improve the quality of life for affected newborns and will also identify babies whose condition may not become symptomatic until permanent damage or disability has occurred.

Review of data on Filipino newborns screened in the California newborn screening program from 2005 to 2011, showed that Filipino newborns confirmed positive with several disorders in the newborn screening panel. The disorders were a mix of endocrinologic and metabolic conditions as well as hemoglobinopathies. (Padilla, 2012)

The data prompted a review and subsequently a formal recommendation of the expanded newborn screening program in the Philippines to the Advisory Committee on Newborn Screening.

In line with the implementation of the expanded newborn screening, a National Technical Working Group (NTWG) was created under the National Center for Disease Prevention and Control (NCDPC) composed of representatives of key offices at the Department of Health and of different concerned institutions. The NTWG was tasked to prepare the necessary guidelines for the implementation of expanded newborn screening in the country.

II. OBJECTIVE

This Administrative Order sets the guidelines for the implementation of the expanded newborn screening in the country.

III. SCOPE AND COVERAGE

Provisions of this Administrative Order shall apply to all Newborn Screening Centers, DOH-Regional Offices, DOH-ARMM, National Comprehensive Newborn Screening System - Treatment Network, health facilities and all other agencies and stakeholders concerned in the implementation of the newborn screening program.

IV. DEFINITION OF TERMS

1. *Confirmatory Center* refers to a facility identified by the DOH to be part of the National Comprehensive Newborn Screening System Treatment Network. It is equipped to do confirmatory testing to ensure the accuracy of screening results.
2. *Newborn Screening Continuity Clinic* refers to an ambulatory clinic based in a tertiary hospital identified by the DOH to be part of the National Comprehensive Newborn Screening System Treatment Network. It is equipped to facilitate continuity of care of confirmed patients in its area of coverage.
3. *National Comprehensive Newborn Screening System Treatment Network* refers to a network wherein total management of patient with confirmed diagnosis shall be referred to. It follows the DOH-approved clinical protocol in the management of patients diagnosed in any of the disorders included in the newborn screening panel.
4. *Newborn Screening Center (NSC)* refers to a facility equipped with a newborn screening laboratory that complies with the standards established by the National Institutes of Health, and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.
5. *Newborn Screening Reference Center (NSRC)* refers to the central facility at the National Institutes of Health that defines testing and follow-up protocols, maintains an external laboratory proficiency testing program, oversees the national testing database and case registries, assists in training activities in all aspects of the program, oversees content of educational materials and acts as the Secretariat of the Advisory Committee on Newborn Screening.
6. *Republic Act 9288: Newborn Screening Act of 2004* refers to the act promulgating a comprehensive policy and a national system for ensuring newborn screening.

V. GENERAL GUIDELINES

1. The number of disorders in the newborn screening panel shall be increased from six (6) to twenty-eight (28) falling under various types of disorders namely: hemoglobinopathies, amino acid disorders, organic acidurias, disorders of fatty acid oxidation, disorders of carbohydrate metabolism, disorders of biotin metabolism, cystic fibrosis, and endocrine disorders.
2. Site renovations/preparations, procurement of equipment and reagents, hiring and training of personnel, upgrading of database, preparation of manuals and protocols,



and implementation of other necessary program groundwork shall be undertaken prior to the implementation of the expanded newborn screening.

3. The necessary confirmatory centers and network for referral, management and treatment of patients found positive under the expanded newborn screening shall likewise be established in strategic areas of the country.
4. Pilot-run of the Expanded Newborn Screening shall be undertaken at the Newborn Screening Center-National Institutes of Health, prior to full implementation before 2015.
5. Newborn screening shall be offered to parents in all participating facilities with two options:
 - a. Option 1: six (6) disorders (CH, CAH, GAL, PKU, G6PD, and MSUD) under the basic NBS panel; and
 - b. Option 2: twenty-eight (28) disorders under the expanded newborn screening panel.
6. Confirmatory centers for the additional disorders shall be identified.
7. A network of specialists shall be identified for the management of the additional disorders.
8. A separate policy shall be issued in the identification of expert panel.
9. Newborn Screening Continuity Clinics shall be set-up to facilitate long term care of patients confirmed through newborn screening.
10. Information on the expanded screening and the disorders included shall be made available to health professionals, parents, and the general public at all NSCs, DOH-Regional Offices and Newborn Screening Facilities.

VI. SPECIFIC GUIDELINES/IMPLEMENTING MECHANISM

In terms of the different components of the newborn screening program, the following shall be considered in the implementation of the expanded screening:

A. Procedure

1. Implementing expanded newborn screening shall involve a series of steps from motivation, screening, follow-up, diagnosis, management and evaluation.
2. As stated in Sec. 6 of the Implementing Rules and Regulations of RA 9288, any health practitioner who delivers, or assists in the delivery of a newborn in the Philippines shall, prior to delivery, inform parents or legal guardian of the newborn of the availability, nature and benefits of NBS. Health practitioners shall follow the DOH prescribed guidelines on notification and education relative to the obligation to inform. The DOH, other government agencies, non-government agencies, professional societies and LGUs shall make available appropriate information materials and shall have a system of its distribution. The health



practitioner shall maintain documentation in the patient's records that NBS information has been provided.

3. Refusal form shall be accomplished by parents refusing newborn screening.
4. The same screening protocol, which includes the proper timing and specimen collection, transport, laboratory testing, and reporting in compliance with the Implementing Rules and Regulation of Republic Act 9288 shall be followed.

B. Reporting and Monitoring Protocols

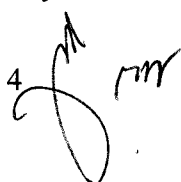
An evaluation plan shall be implemented that would clearly define selected indicators, assign responsibility for monitoring, and outline the periodicity with which evaluations are to occur. The program evaluation shall encompass the detailed procedures, operational arrangements and budget source.

C. Roles and Responsibilities

To ensure implementation of expanded NBS, the agencies/organization identified below shall have the following responsibilities:

1. The Department of Health

- a. The FHO shall be the lead agency in the implementation of expanded newborn screening. Its roles and responsibilities are stated in Section 13 of the Implementing Rules and Regulations of RA 9288.
- b. The FHO, as the lead in the National Technical Working Group (NTWG) on Newborn Screening shall ensure that the expanded screening is integrated into the NTWG's various functions of long-term or medium-term target setting and planning. This shall ensure that all policies, guidelines and standards of the expanded screening program adhere to over-all internationally accepted standards and ethical considerations. Specifically, expanded screening shall be included in the NTWG's functions of:
 - i. Developing/reviewing policies, standards and guidelines on Newborn Screening for recommendations to and approval of the Advisory Committee of the Newborn Screening Program;
 - ii. Recommending the disorders to be included in the Newborn Screening panel;
 - iii. Reviewing and recommending the Newborn Screening fee to be charged by the Newborn Screening Centers;
 - iv. Developing/reviewing strategies and tools that ensure effective and efficient implementation of the Newborn Screening at various levels;
 - v. Formulating national program / project plan, proposals and collaborative studies on Newborn Screening; and
 - vi. Reviewing the report of the Newborn Screening Reference Center on the performance of the Newborn Screening Centers and recommended corrective measures as deemed necessary.

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- c. The Health Promotion and Communications Service (HPCS), in coordination with the NSRC, shall be responsible for advocacy and information dissemination on expanded screening to the communities throughout the country prior to and during the implementation of expanded screening.

2. Health Facilities

Health facilities, i.e. hospitals, birthing facilities, rural health units and health centers, shall ensure that the expanded newborn screening is offered as an option. It shall be integrated in their Newborn Screening Services and provision of information, education, communication, screening, recall and management of identified cases and other related services, as outlined in Section 14 of the IRR of RA 9288, shall be undertaken.

3. Newborn Screening Reference Center

NSRC shall define the testing and follow-up protocols for the additional disorders; maintains an external laboratory proficiency testing program, and integrating the additional disorders in its case registries and national testing database it oversees; assists in training activities in all aspects of the NBS program.

4. Newborn Screening Centers

NSCs shall ensure that laboratory space, equipment and supplies needed for the implementation of the expanded newborn screening are in place. It shall ensure that the mechanism for ordering and payment of expanded newborn screening service is in place. It shall ensure that patients identified positive in any of the disorders are followed up and referred to specialists for initial management. All NSC's shall strictly follow the prescribed guidelines of good laboratory practices.

5. Newborn Screening Continuity Clinics

Newborn Screening Continuity Clinics shall facilitate continuous care of confirmed positive patients. It shall provide long-term follow-up care activities related to improving care delivery, including engagement of affected individuals and their families.

D. Budget Source

1. The NBS Fee

- a. The cost of the tests shall be as follows (*Per recommendation of the Advisory Committee on Newborn Screening on August 19, 2012*):

Option 1 (6 disorders) - Php550.00

Option 2 (expanded newborn screening) - Php1,500.00.

- b. For PhilHealth members, P550 shall be covered by PhilHealth.

For Option 1 (6 disorders), the total cost shall be covered.

For Option 2 (expanded NBS), only P550 shall be covered by PhilHealth and the balance shall be an out-of-pocket expense of the family.



- c. Both options 1 and 2 shall have an allowable charge of P50 for the collection of the sample (*DOH AO No. 2005-005*).
- d. Overpricing of newborn screening fees shall be reported to the Department of Health. The following administrative fines shall be imposed on health facilities that were found liable for collecting more than the maximum allowable NBS fees (*DOH AO 2008-0026-A*):
 - First offense - Warning
 - Second offense - Administrative fine of fifty thousand pesos (P50,000)
 - Third offense - Administrative fine of one hundred thousand pesos (P100,000)

2. Usage of the NBS Fee

As stated in Section 22 of the Implementing Rules and Regulations of RA 9288, the NBS fee shall be applied to, among others, testing costs, education, sample transport, follow-up and reasonable overhead expenses.

VII. REPEALING CLAUSE

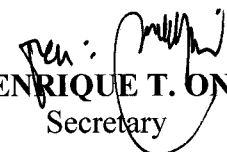
Provisions of AO No. 121 s. 2003 and all other issuances that are inconsistent with the provisions of this Order are hereby repealed /rescinded.

VIII. SEPARABILITY

If any provision of this Order is declared invalid, the other provisions not affected thereby shall remain valid and subsisting.

IX. EFFECTIVITY

This Order shall take effect fifteen (15) days after its approval and publication in the official gazette or newspaper of general circulation.

Pen: 
ENRIQUE T. ONA, MD
Secretary