

## 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 DOH 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 DOH, 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 overall 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.

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, maintain an external laboratory proficiency testing program, integrate the additional disorders in its case registries and national testing database it oversees, and assist 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 NSCs 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): Php 550.00

Option 2 (expanded newborn screening): Php 1,500.00

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 administrative fines shall be imposed on health facilities that collect more than the maximum allowable NBS fees (DOH AO 2008-0026-A):

First offense - Warning

Second offense - Administrative fine of fifty thousand pesos (P50,000.00)

Third offense - Administrative fine of one hundred thousand pesos (P100,000.00)

##### 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.

  
**ENRIQUE T. ONA, MD**  
Secretary

## ERRATUM

In Issue 4 (July-August), the article *NBS Trainings and Refresher Courses in CARAGA and Region XI* on page 4 contained text from an article in the previous issue (*Parents Forum Held in Three Cities*).

We apologize for this mistake. Please check the updated edition at [www.newbornscreening.ph](http://www.newbornscreening.ph).

## ADMINISTRATIVE ORDER NO. 2014-0035

Subject: Implementing Guidelines on the Setting-up of Newborn Screening Continuity Clinics

### I. Rationale

Pursuant to Section 13 of the Implementing Rules and Regulation of Republic Act 9288, otherwise known as the Newborn Screening Act of 2004, the DOH being the lead agency shall ensure that a network of facilities for referral and management of all positive cases is established. In addition, it shall develop referral centers and identify referral teams in strategic areas for referral and management of patients with any of the disorders.

Recognizing this need and of the mandate to develop referral centers, the Department of Health and the National Institutes of Health are setting up Newborn Screening (NBS) Continuity Clinics in the country to strengthen the National Comprehensive Newborn Screening System Treatment Network and ensure the early treatment and appropriate management of identified positive cases.

Initially, one Newborn Screening Continuity Clinic and Birth Defects Continuity Clinic per region shall be set up. Subsequently, provincial continuity clinics shall be established.

### II. Objective

To provide policies and guidelines for the setting up and implementation of NBS Continuity Clinics and Birth Defects Continuity Clinics for referral and management of all screened-positive newborns.

### III. Scope and Coverage

This Order shall apply to all Newborn Screening Centers, DOH-Regional Offices (DOH-ROs), National Comprehensive Newborn Screening System Treatment Network, and all other agencies and stakeholders concerned in the implementation of the newborn screening program.

### IV. Definition of Terms

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.

National Institutes of Health–Institute of Human Genetics (NIH-IHG) refers to the unit at the National Institutes of Health that provides comprehensive clinical evaluation of families or individuals with or at risk for heritable conditions; it provides support for remote, real-time referral (the Telegenetics Referral System) and Birth Defects Surveillance System in the country. It also offers laboratory and diagnostic services pertinent to the management of heritable conditions.

Newborn Screening Panel of Disorders refers to the list

of disorders tested under the Philippine Newborn Screening Program. The panel includes newborn screening for the following disorders: Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Phenylketonuria, Galactosemia, G6PD Deficiency, and Maple Syrup Urine Disease. By mid-2014, an expanded newborn screening panel shall be offered as an option increasing the number of disorders from six (6) to twenty-eight (28) falling under various types of disorders, namely, hemoglobinopathies, amino acid disorders, organic acid disorders, disorders of fatty acid oxidation, disorders of carbohydrate metabolism, disorders of biotin metabolism, cystic fibrosis, and endocrine disorders.

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.

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 required laboratory tests and recall/follow-up programs for newborns with heritable conditions.

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.

Birth Defects Continuity Clinic refers to an ambulatory clinic based in regional and provincial referral centers identified by the DOH. It specifically caters to patients with birth defects for the purpose of diagnosis and management.

Telegenetics Referral System refers to provision of remote genetic clinical consults to physicians in the provinces for their patients over a computer network.

### V. General Guidelines

A. The NBS Continuity Clinics shall be established, initially in every region, equipped to facilitate continuity of care of confirmed patients in its area of coverage. Subsequently, the NBS Continuity Clinics shall be established in the provincial level.

B. The Birth Defects Continuity Clinics shall be integrated in the National Comprehensive Newborn Screening System. The Birth Defects Continuity Clinics will share the same infrastructure and personnel of the Newborn Screening Continuity Clinics.

C. The Telegenetics Referral System shall be utilized by the NBS Continuity Clinics and Birth Defects Continuity Clinics where subspecialists are not available in the hospital.



D. Memoranda of Agreement shall be executed between NSRC, NSC, DOH-RO, Host Facility, and IHG for every regional/provincial Continuity Clinic.

## VI. Specific Guidelines

### A. Patient Care

In terms of the different components of NBS patient care, the following shall be considered in the implementation of the NBS Continuity Clinics and Birth Defects Continuity Clinics:

#### 1. Diagnosis and Initial Management

a. In coordination with the DOH-ROs, the NSCs shall be responsible for the tracking of newborns with out-of-range screening results to ensure repeat specimen collection, repeat screening and/or confirmatory testing from the NBS laboratories or confirmatory centers.

b. The NSCs shall facilitate the confirmatory testing for newborns with out-of-range screening results and initiate medical management for patients with confirmed diagnosis.

2. Long-term Management (including counseling, treatment, monitoring, and follow-up).

a. The NSCs shall refer all newborns who are confirmed positive with heritable disorders to NBS Continuity Clinic for long-term follow-up care.

b. In coordination with the DOH-ROs, every effort shall be made by the personnel of the continuity clinics to contact and schedule patients referred from NSCs so that the necessary treatment and long-term follow-up care shall be given, as well as timely monitoring shall be undertaken.

c. The continuity clinics shall facilitate referral of patients needing consults to available subspecialists in their facility or region. In cases wherein subspecialists are not available, the continuity clinics shall utilize the Telegenetics Referral System.

### B. Operations of NBS Continuity Clinics

In terms of the different components of the newborn screening program, the following shall be considered in the implementation of the NBS Continuity Clinics and Birth Defects Continuity Clinics:

#### 1. Selection, Recruitment, and Hiring of Personnel

a. The continuity clinics shall be manned by a part-time Medical Specialist and a full-time Nurse or Genetic Counselor.

b. The Department of Pediatrics of every host facility shall be responsible for overseeing the recruitment and selection of personnel for the continuity clinic in their facility.

c. The host facility shall make the necessary recommendations for the hiring of their personnel.

### 2. Funding

The operational expenses of these clinics, including, but not limited to, communication and travel expenses, as well as financial support for indigent families, shall be shared responsibilities of NSRC, NSCs, DOH-ROs, and host facilities.

### C. Capacity Building

Long-term management of patients and required enhancement of skills and competencies will be supported with a capacity-building program organized by the DOH in partnership with NSRC.

### D. Information Education and Communication

1. Information on the establishment of the continuity clinics and the Telegenetics Referral System shall be disseminated to all agencies concerned;

2. Information on the long-term follow-up treatment and management of the disorders included in the NBS panel shall be made available to health professionals, parents, and the general public at all continuity clinics, NSCs, and DOH-ROs.

### E. Monitoring and Evaluation

A monitoring and evaluation plan shall be developed to provide the mechanism for monitoring and evaluation of the continuity clinics implementation and the key indicators for impact monitoring.

### F. Roles and Responsibilities

#### 1. Department of Health

The DOH 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.

#### a. Family Health Office shall:

1. Review and update guidelines on the operations of the NBS Continuity Clinics and Birth Defects Continuity Clinics.

2. Formulate and issue a monitoring and evaluation tool pursuant to the operations of these clinics.

#### b. Regional Offices shall:

1. Establish a mechanism for recall of confirmed patients for referral to experts for management and follow-up care;

2. On the basis of availability of funds, provide indigency support for confirmatory testing of patients with significantly elevated laboratory results and for treatment and long-term management of confirmed patients in the region.

#### 2. Newborn Screening Reference Center shall:

#### a. Oversee the implementation of activities of NBS

### Continuity Clinics and Birth Defects Continuity Clinics;

b. Secure monthly, quarterly, and yearly reports from participating units and ensure their timely dissemination to various program stakeholders;

c. Participate in consultation and evaluation activities initiated by the DOH in relation to the NSRC and the NBS Continuity Clinics' and Birth Defects Continuity Clinics' performance and in improving of rules and regulations;

d. Assist in the training activities of the program;

e. Oversee and review content of educational materials as well as the production of the materials.

#### 3. Newborn Screening Centers shall:

a. Give diagnosis, make proper referral, and initiate management for all confirmed NBS patients;

b. Provide roster of confirmed patients, including their protocols for management and list of follow-up laboratory procedures, to the NBS Continuity Clinic.

#### 4. Host Facilities of NBS Continuity Clinics shall:

a. Set up NBS Continuity Clinic and Birth Defects Continuity Clinic;

b. Provide a clinic space for patient consultation and a work station for the follow-up nurse and/or genetic counselor.

c. Oversee the selection and hiring of personnel for the NBS Continuity Clinic in their facility;

d. Integrate NBS continuity clinic to the current services of the host facility;

e. Ensure the sustained operation of NBS Continuity Clinic and Birth Defects Continuity Clinic according to the Operational Guidelines set by the Department of Health and the Newborn Screening Reference Center for these clinics.

#### 5. Institute of Human Genetics shall:

a. Strengthen the surveillance program for newborns with birth defects in the country;

b. Establish systems for the referral of patients with birth defects from BDS health facility to Birth Defects Continuity Clinics;

c. Provide support in the operations of Telegenetics Referral System;

d. Establish an efficient system in the procurement and availability of medicines, medical food and other medical requisites needed in the management of patients with birth defects and confirmed patients detected through newborn screening.

## VII. Repealing Clause

All orders and issuances, rules, and regulations or parts thereof inconsistent with the provisions of this Order are hereby amended, modified, or repealed accordingly.

## VIII. Separability Clause

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.

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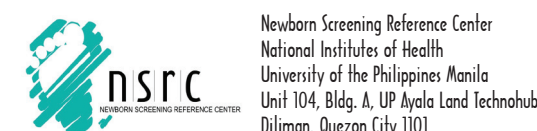
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If you would like to write an article, please contact us at [info@newbornscreening.ph](mailto:info@newbornscreening.ph). We will do our best to keep you informed about current and relevant newborn screening issues.



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VOLUME 18  
ISSUE  
**06**  
NOVEMBER-  
DECEMBER  
2014



# newborn screening

Bimonthly Publication of the Newborn Screening Reference Center  
National Institutes of Health, University of the Philippines Manila

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Number of Babies Screened as of December 2014

COUNTER: 6,222,468



Secretary Enrique T. Ona during the Women Deliver Conference in Kuala Lumpur on May 29, 2013.  
Photo by Karen Galarpe as it appears on [gmanetwork.com](http://gmanetwork.com)

## DOH Releases Two New NBS Policies

The Department of Health (DOH), through the leadership of Secretary of Health Dr. Enrique T. Ona, released two issuances in 2014 promoting and strengthening the newborn screening program in the Philippines.

The latest policy in 2014 that touched on the newborn screening was Administrative Order (AO) No. 2014-0045, or the Guidelines on the Implementation of the Expanded Newborn Screening Program, which was signed on November 19, 2014.

AO 2014-0045 laid down the rules and procedures on how the expanded newborn screening should be implemented on all levels, including local, regional, and national.

Meanwhile, AO No. 2014-0035, which was signed on October 30, 2014, was about the Implementing Guidelines on the Setting-up of Newborn Screening Continuity Clinics.

The order provides for the setting up and implementation of NBS Continuity Clinics and Birth Defects Continuity Clinics for referral and management of all screened-positive newborns.

Both AOs apply to all Newborn Screening Centers, DOH-Regional Offices, National Comprehensive Newborn Screening System Treatment Network, and all other agencies and stakeholders concerned in the implementation of the newborn screening program.