



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

NOV 05 2018

**ADMINISTRATIVE ORDER**

No. 2018 - 0025

**SUBJECT: National Policy and Strategic Framework on Expanded Newborn Screening for 2017 - 2030**

**I. BACKGROUND AND RATIONALE**

For two decades, the Newborn Screening (NBS) program has successfully laid its foundation by integrating the program to the existing health system and infrastructure as outlined in the NBS strategic framework. Workshops for strategic planning on NBS were conducted in 2001 and 2009, respectively. Initially, the focus was on building the foundation for the NBS program and how it will be implemented in major facilities. Later on, the program aimed to increase the national coverage by continuous implementation of NBS to the rest of the facilities nationwide and integration to the service delivery network through policies and advocacies.

Today, the National Comprehensive Newborn Screening System (NCNBSS) thrust in the next thirteen years is to ensure the sustainability of NCNBSS, including the full shift to expanded newborn screening and the provision of continuing care for confirmed patients for any of the screened disorders. Several policies were released in 2014 in pursuit of these thrusts such as Administrative Order No. 2014-0045, which set the guidelines on the implementation of the Expanded Newborn Screening (ENBS) program and provided the option for parents to avail between the 6-test and ENBS test; and the DOH Administrative Order 2014-0035 that facilitated the initial establishment of the NBS Continuity Clinics in 14 regions to facilitate continuity of care of confirmed patients in their area of coverage.

The Department of Health (DOH) in coordination with its program partners reconfigured the NCNBSS framework for 2017-2030 to provide direction and to intensify the implementation, especially the ENBS. The plan shall concretize the long-term goals of the NCNBSS.

**II. OBJECTIVES**

This Order aims to:

1. Provide a strategic framework for the implementation of the Expanded Newborn Screening Program from 2017-2030; and
2. Provide policy direction and guidance for DOH offices, its attached agencies, LGUs, and development partners in prioritizing interventions for the health of newborns.

**III. COVERAGE AND SCOPE OF APPLICATION**

This Order shall apply to the entire public and private health system, including DOH bureaus, Regional Offices (ROs), hospitals and other health facilities, attached agencies, local government facilities, external development partners and other stakeholders implementing health programs for and with pregnant women, mothers and newborns.

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#### **IV. DEFINITION OF TERMS**

1. Newborn Screening is an essential public health strategy that enables the early detection and management of several congenital disorders (metabolic and endocrine disorders, hemoglobinopathies, and cystic fibrosis), which if left untreated, may lead to mental retardation, disability and/or death.
2. Long term management system is the provision of appropriate management, intervention and support services to all confirmed cases of NBS disorders to enable optimal, physical, mental and social outcomes for these individuals.

#### **V. GENERAL GUIDELINES**

1. The National Policy and Strategic Framework on Expanded Newborn Screening for 2017-2030 shall guide healthcare interventions on newborn screening to be able to attain the following targets by 2030:
  - a. At least 95% national coverage of the expanded newborn screening;
  - b. At least 90% of health facilities with maternity and newborn services that includes expanded newborn screening;
  - c. At least 95% monitoring data are generated from regional offices and Newborn Screening Facilities (NSFs) through online monitoring system;
  - d. 100% ISO certification of all newborn screening centers and newborn screening reference center;
  - e. 100% of comprehensively trained and certified personnel who will perform NBS collection in NSFs;
  - f. At least 95% of regions maintained 99% satisfactory sample collection rate;
  - g. 100% PHIC coverage of the newborn care package to include ENBS;
  - h. At least 85% of identified strategically located provinces with established long-term management system for NBS confirmed positive patients.

#### **2. STRATEGIC FRAMEWORK**

The Newborn Screening Program is guided by the following principles: (a) integration with all child health programs; (b) evidence-based interventions/approach, quality; and (c) sustainability and partnership and shared responsibilities. The Strategic Framework for Newborn Screening directs the program for the next 13 years and is aimed to ensure the sustainability and nationwide implementation of expanded newborn screening program through actionable program components and variety of strategies (See ANNEX A).

The shift from the six-panel screening into an expanded screening for 28+ panel of heritable disorders would entail upgrading, strengthening and sustaining the different program components with the end result of delivery of quality services through ISO certified facilities and reaching out to every infant in the community. The service is not limited to screening alone but long-term management of children who are confirmed positive for congenital disorders.

3. The targets are to be achieved through the following strategies:

**STRATEGIES** (See Strategic Plan in Annex D)

**I. Ensuring Efficient Operations, Systems and Networks Management**

This shall be upgraded to reach areas that need access to newborn care. This includes construction and/or renovation of well-planned and equipped infrastructures to ensure quality service among patients and to engage more health facilities to offer NBS services (human resource for health-trained and capacitated)

- a. Development of Manual of Operations and Standards from screening, confirmatory testing to referral and management.
- b. ISO 15189:2012 Certification of all Newborn Screening Centers (NSCs).
- c. Information dissemination geared towards importance and regulation of testing in confirmatory centers.

**II. Expanding Package of Services and Delivery Network**

In the next ten years, the program aims to shift fully into expanded newborn screening. Enrollment of new facilities and sustaining the operations of existing facilities is critical in increasing the coverage of service delivery. Strategic actions to increase the uptake of ENBS are critical to ensure nationwide implementation, which involves strong promotion, advocacy and cooperation of the newborn screening facilities.

- a. Opening of additional three NSCs shall ensure expedient sending and receiving of results to and from geographically isolated and disadvantaged facilities.
- b. Setting up of continuity clinics and referral system in the provinces to further strengthen the referral and management network of positive cases in the hope that no patient will be deprived of long term care.
- c. Strict enforcement of newborn screening policies to ensure delivery of sustainable ENBS service at the national level down to local level.
- d. Enhancement of diagnosis, follow up, and management of confirmed cases through prompt recall and confirmatory tests of patients by effective utilization of service delivery network for appropriate referral and management of patients, collaborative partnerships and assessment of recall and follow up protocols.
- e. Training and deployment of clinical geneticists, pediatric endocrinologists and genetic counselors at the provincial level.

- f. Develop human resource complement positions at the DOH and Local Government Units (LGUs) to ensure that nurses, doctors and other health professionals working in the continuity clinics and regional offices are given plantilla positions.

### **III. Enhancing Health Promotion and Advocacy**

This requires a developed and well-coordinated comprehensive health promotion and communication plan targeting different audiences to increase awareness and uptake on expanded newborn screening. It shall also focus on information campaign by strengthening communication strategies using different media platforms.

- a. Develop an ENBS national communication plan to increase the uptake of ENBS nationwide.
- b. Strengthen alliance building with different organizations and Local Government Units (LGUs).
- c. Integrate ENBS in the academic curriculum with other health related subjects in the secondary and tertiary levels, specifically in Grade 8 level.
- d. Intensify training and development of innovative training materials for newborn screening with post training evaluation.

### **IV. Optimizing Health Information Management Systems for Expanded Newborn Screening**

This aims to optimize current investments on health management information systems by adopting interoperable, consensus-based, evidence-driven and standards-based vocabularies and system that maximize the use of electronic health record systems that will automatically process and send information and reports to (a) PhilHealth for verification of claims for NBS, and (b) the NBS registry for program planning and research purposes, among others.

- a. Establish efficient national database and case registries for real-time generation of data.
- b. Develop and implement online monitoring system for easy access of data.

### **V. Strengthen Monitoring and Evaluation**

Program monitoring and evaluation of procedures and systems, both for laboratory and administrative units shall be undertaken to ensure smooth implementation of the program. Periodic review of monitoring and evaluation tools should be done including quality assurance assessment.

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- a. Modify NBS evaluation tools such as the Philippine Performance Evaluation Assessment System (PPEAS) tools for NSCs, ROs, Continuity Clinics and NSFs for periodic assessment.
- b. Conduct program review, audit and evaluation procedures and systems for both laboratory and administrative units.
- c. Establish local QA laboratory for the monitoring and evaluation of Newborn Screening Centers (NSCs).

## **VI. Establishing Sustainable Financing Scheme**

The DOH, as the lead agency of the NBS program shall allocate funds for the set-up of new strategically-located newborn screening centers. The National Comprehensive Newborn Screening System (NCNBSS) also ensures funding for researches relevant to the implementation of newborn screening at the national level that maybe utilized for policy recommendations. The Philippine Health Insurance Corporation (PHIC) also ensures full coverage of expanded newborn screening, while LGUs and other stakeholders and partners are empowered to provide ways or means to make the NBS accessible and affordable, particularly on the economically depressed areas.

- a. Include full coverage of ENBS in the Philhealth newborn care package.
- b. Provide funds for research grants for policy recommendation on NBS.
- c. Building alliance with LGUs and other institutions/agencies to allot budget for screening, confirmatory tests and management in the continuity clinics by having a community financing schemes and programs.
- d. Continuous collaboration to include NBS program in the Department of Health investment plan and allot budget for the needs of newborn screening from the national fund including health promotion and communication campaign at all levels using different media platforms.

## **VI. IMPLEMENTING MECHANISMS**

The DOH Central Office shall act as the lead agency, along with the LGUs, for the implementation of this Order. The Advisory Committee on Newborn Screening (ACNBS) is the inter-agency body that reviews and recommends policies and standards to the Secretary of Health. The DOH created a Technical Working Group on Expanded Newborn Screening whose primary role is to oversee the implementation of the Program and monitor progress based on the M&E Framework. (see ANNEX B).

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The following summarizes the roles and functions of the different groups of stakeholders that have critical roles in the Newborn Screening Framework 2017-2030:

- a. **DOH – Disease Prevention and Control Bureau** shall undertake the following tasks:
  - Disseminate the strategic framework and enabling policies to ensure implementation of the strategies;
  - Mobilize funds and various resources of various offices and agencies for the set-up of strategically located new newborn screening centers, confirmatory centers, and continuity clinics all over the country.
  - Provide human resource complement through the provision of plantilla positions for nurses, doctors and other health professionals to assure availability of dedicated and committed staff.
  - Provide technical inputs/assistance in developing a health promotion and communication plan & materials for ENBS in collaboration with HPCS and NIH-NSRC to educate health professionals and the general public.
  - Oversee the conduct of regular monitoring and evaluation of the program implementation;
  
- b. **DOH – Health Facilities and Services Regulatory Bureau (HFSRB)**
  - Include certification from NSRC as part of licensing requirement for hospitals and birthing facilities;
  - Include NBS in their monitoring compliance in giving license to operate to hospitals and birthing facilities; and
  
- c. **DOH – Health Human Resource Development Bureau (HHRDB)** Provision of human resource complement through the provision of plantilla positions for nurses, doctors and other health professionals to assure availability of dedicated and committed staff is beyond the DOH capacity;
  - Develop competency-based modules on NBS for health service providers
  - Map potential partner institutions to deliver NBS courses per region and per province.
  - Monitor the learning and development of NBS providers in coordination with the Regional Office Program Coordinators and Training Specialists.
  
- d. **DOH – Health Promotion and Communication Service (HPCS)** shall develop comprehensive Newborn Screening health promotion and communications plan including prototype information, education & communication (IEC) materials and collaterals in coordination with DPCB –FHO and NIH – NSRC to facilitate advocacy for expanded newborn screening.
  
- e. **DOH – Knowledge Management Information Technology Service (KMITS)** shall provide technical assistance in the (a) development, integration and maintenance of interoperable, consensus-based, evidence-driven and standards-based vocabularies and system module on NBS in electronic health record system; (b) development and maintenance of an NBS registry; and (c) facilitate and ensure interoperability of these HER systems with the NBS registry and other relevant information systems to facilitate knowledge management and timely decision-making.

f. **DOH Regional Offices and DOH ARMM** are the implementing arm of the Department of Health in the regional level and ARMM, where each has a designated Newborn Screening (NBS) Coordinator to facilitate and collaborate the full implementation of the program by the participating health units at the local level. The coordinators should be responsible of the following tasks:

- Disseminate the strategic plan and enabling policies to LGUs and agencies in the regions.
- Lead in the conduct of comprehensive training and orientations to hospitals, health organizations and the community;
- Assist in all health information and advocacy activities, particularly in the promotion of ENBS;
- Monitor and assist the recall of patients for immediate tracking and retrieval of positive screening for confirmatory testing, referral and proper management; and

g. **Department of Interior and Local Government (DILG) in Regional Offices and ARMM**

- Encourage LGUs to implement RA 9288 and extend total cooperation in the implementation of the said law.
- Assist DOH in the monitoring and evaluation of the program implementation.

h. **Local Government Units (LGUs) of Regions and ARMM**

- Develop the capabilities of health workers;
- Issue local ordinances and resolutions that integrate NBS in the delivery of health delivery system;
- Ensure that adequate and sustained NBS services such as information, education, communication, screening, recall and follow-up are being provided in all LGU Health facilities (Rural Health Unit/ City Health Unit, Lying-ins, City/Municipal/ District/Provincial Hospitals);
- Establish a functional case management referral system with strategically accessible NCNBSS treatment network;
- Establish coordination and networking among concerned agencies in NBS implementation;
- Monitor and evaluate the newborn screening implementation in their localities;
- Explore/encourage creative financial packages to make NBS accessible particularly among the economically deprived populace; and
- Perform other roles and responsibilities as deemed necessary for the implementation of this Act.

i. **Philippine Health Insurance Corporation (PhilHealth)**

- Include proof of newborn screening services in their checklist for the accreditation of health facilities for quality newborn and pediatric services; and
- Facilitate increase of benefit package for newborns, covering the expanded newborn screening service.

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- j. Department of Education (DepEd) and Commission on Higher Education (CHED)** shall assist the DOH on the integration of newborn screening policy in the curriculum to be implemented by the schools and higher education institutions at basic, secondary and tertiary levels.
- k. Newborn Screening Reference Center (NSRC)** is the central facility that provides technical assistance to the Department of Health. It shall do the following:
- Provide technical assistance in setting up NSCs including training and capability building;
  - Define testing and follow-up protocols;
  - Maintain an external laboratory proficiency testing program
  - Advocate and disseminate importance of taking confirmatory tests through creation and distribution of IEC materials;
  - Allocate funds for the fellowships to ensure the availability of qualified health personnel (e.g. Clinical Geneticists and Pediatric endocrinologists) who could be tapped by the NCNBSS in the follow-up treatment and monitoring for prompt and proper management of newborn babies screened positive.
  - Develop IEC materials and training modules among others, for dissemination to partners and facilities, for ENBS promotions;
  - Oversee the national testing database, case registries and content of educational materials;
  - Create a plan for long-term outcome evaluation of NBS utilizing the case registries;
  - Conduct regular monitoring and evaluation of the program
  - Assist in the national training activities of the program; and
  - Process the transfer of funds to the regional offices
- l. Newborn Screening Centers** are the facilities equipped with a newborn screening laboratory that comply with the standards established by the National Institutes of Health (NIH) and are responsible to the following tasks:
- Create capability building plan and activities;
  - Provide financial support to continuity clinics;
  - Conduct all required tests for all newborn screening samples received;
  - Coordinate immediate recall or short-term follow up of newborns with heritable conditions to sending NSF's and DOH ROs and DOH ARMM; and
  - Participate in the follow-up programs of newborns screening.
- m. Newborn Screening Host Facility** lodged in health facilities shall provide for the venue or space for newborn screening centers.
- n. Newborn Screening Facility** implements the NCNBSS at the community level, which are responsible for the following tasks:
- Integrate NBS in its delivery of health services specifically maternal and newborn services
  - Serve as collecting health facility for NBS
  - Coordinate with the duly accredited NSC covering their area
  - Ensure that that adequate and sustained NBS services such as information, education, communication, screening, recall and management of identified cases are being provided in the hospital;



- Establish a NBS Team that will be responsible for the following: collection of samples, sending of samples to accredited NSC, prompt recall of positive patients, referral and management of patients;
- Establish an appropriate financial system that will ensure effective and efficient collection of fees and payment of NBS services to the NSC;
- Conduct orientation and/or training of hospital staff on NBS;
- Monitor and evaluate the implementation of NBS within in the institution;
- Define creative financial packages to make NBS accessible particularly among the economically deprived populace.

#### **VII. REPEALING CLAUSE**

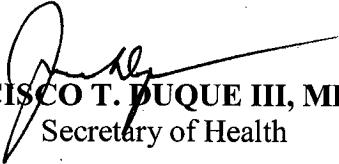
The provisions of previous Orders and other related issuances inconsistent or contrary with the provisions of this Administrative Order, including AO No. 2014-0045 are hereby revised, modified, repealed or rescinded accordingly. All other provisions of existing issuances which are not affected by this Order shall remain valid and in effect.

#### **VIII. SEPARABILITY CLAUSE**

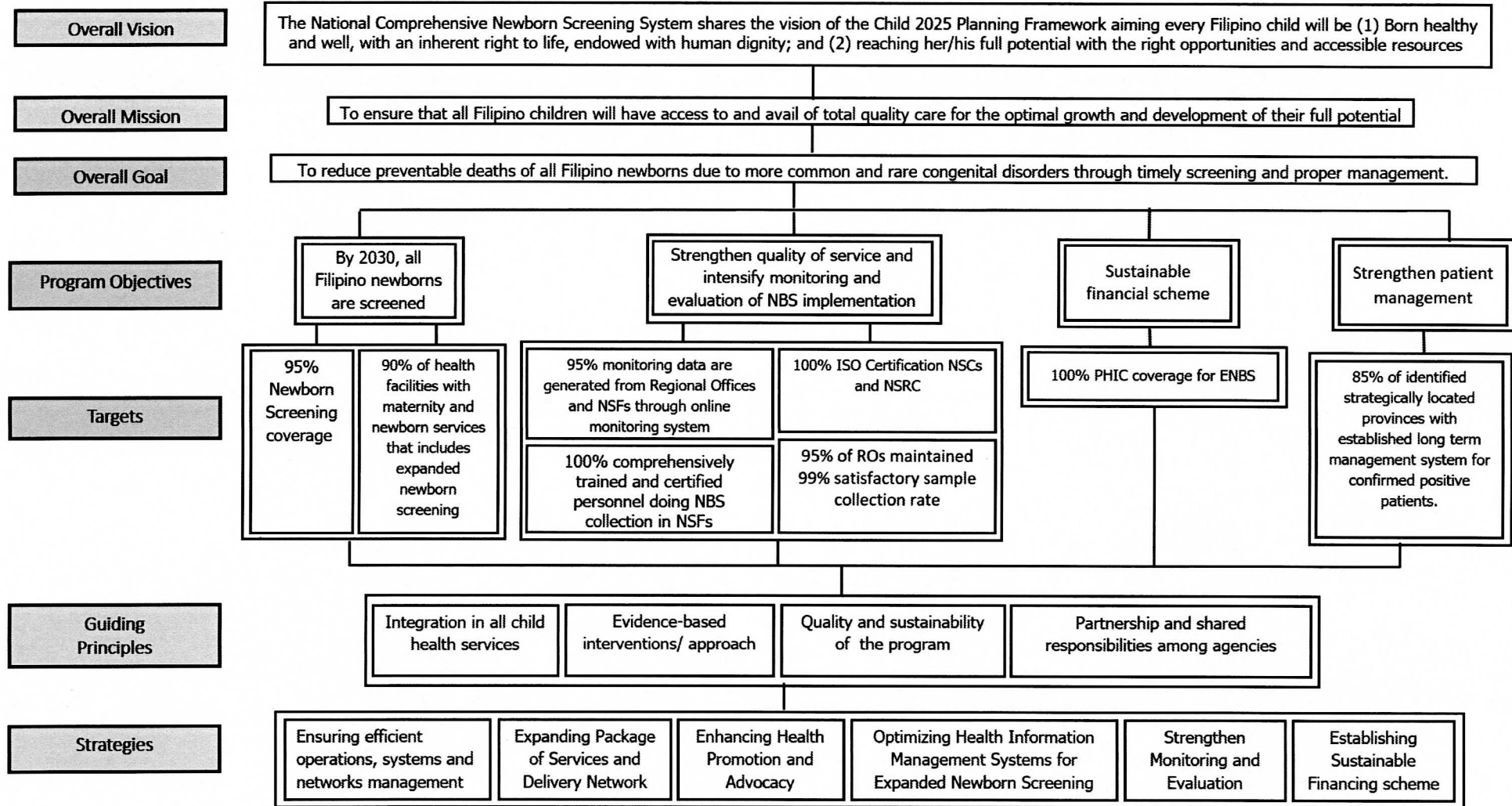
If any provision of this Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

#### **IX. EFFECTIVITY**

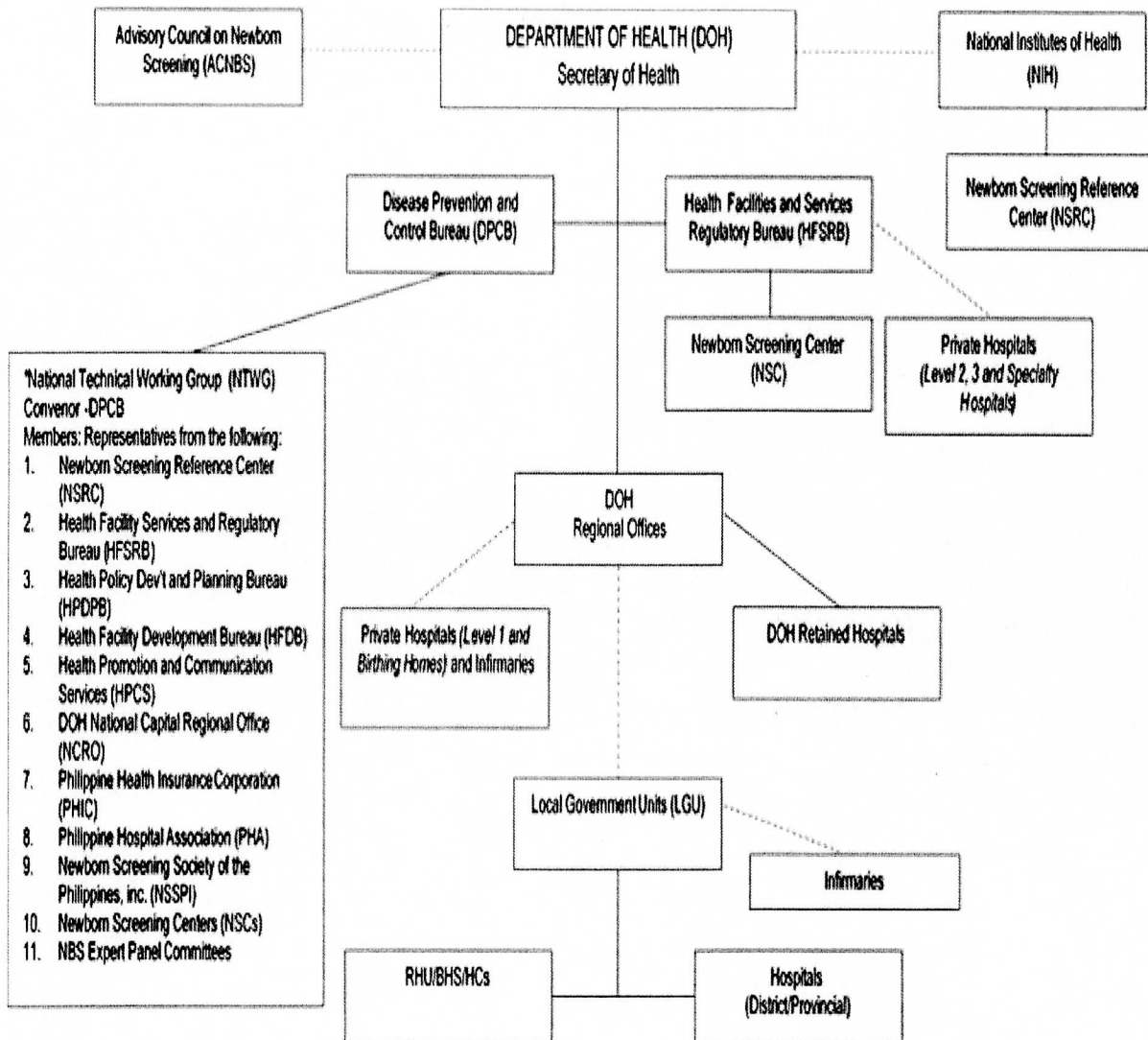
This Order shall take effect immediately.

  
**FRANCISCO T. DUQUE III, MD, MSc**  
Secretary of Health

# Annex A: Strategic Framework



## Annex B: Newborn Screening Program Organizational Structure



### Newborn Screening Program Organizational Structure

(As agreed during the August 11, 2017 NTWG on Newborn Screening Meeting)

## **Annex C: Legal Frameworks/Mandates**

1. Republic Act 9288 or Newborn Screening Act of 2004 – an act promulgating a comprehensive and national system for ensuring newborn screening
2. Implementing Rules and Regulations of RA 9288 – promulgates the implementation of RA 9288
3. AO No. 1-A 2000 – Policies on the Nationwide Implementation of Newborn Screening
4. AO No. 121 s 2003 – Strengthening Implementation of the NBS System
5. AO No. 2005-005 – Cost of the NBS and Maximum Allowable Service Fees for the collection of NBS samples in all NSCHF
6. AO No. 2007-0027 – Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Lab in the Philippines
7. AO No. 2009-0025 – Policies and Protocol on Essential Newborn Care
8. AO No. 2009-0028 – Designation of the NSRC, NIH-UPM to Oversee the Quality Assurance Program for G6PD Test
9. AO No. 2012-0017 – Dried Blood Spots Guidelines
10. AO No. 2013-0015 – Guidelines on the Newborn Screening DOH CHD and ARMM 4% Fund Utilization
11. AO No. 2014-0035 – Implementing Guidelines on the Setting-up of NBS Continuity Clinics
12. AO No. 2014-0045 – Guidelines on the Implementation of the Expanded NBS Program
13. AO No. 2008-0029 – Implementing Health Reforms for Rapid Reduction of Maternal & Neonatal Mortality
14. AO No. 2009-0028 – Designation of the NSRC, NIH-UPM to Oversee the Quality Assurance Program for G6PD Test
15. Dept. Order No. 29-C s. 2001 – Creation of NTWG on NBS Program
16. DM No. 59 s. 2004 – Establishment and Accreditation of NSCs
17. DM No. 2007-0108 – Ensuring that all newborns shall have access to Newborn Screening
18. DM No. 2008-0020 – Reiterating the Provision of NBS Services as a Mandatory Licensing Requirement for all Hospitals
19. DM No. 2008-0114 – G6PD Confirmatory Laboratories
20. DM No. 2009-0025 – Hiring of Full-time Staff Coordinators for the NBS Program

**Annex D:**

<b>STRATEGIC PLAN FOR EXPANDED NEWBORN SCREENING GANTT CHART 2017-2030</b>						
<b>Strategies</b>	<b>Major outcome/action points</b>	<b>Baseline 2017</b>	<b>2018-2020</b>	<b>2021-2023</b>	<b>2024-2026</b>	<b>2027-2030</b>
Ensuring efficient operations, systems and networks management	Development of Manual of Operations and Standards from screening, confirmatory testing to referral and management.					
	ISO 15189:2012 Certification of all NSCs.	1 NSC was ISO Certified (NSC-NIH)				
	Information dissemination geared towards importance and regulation of testing in confirmatory centers.					
Expanding Package of Services and Delivery Network	Opening of additional three NSCs shall ensure expedient sending and receiving of results to and from geographically isolated and disadvantaged facilities.	6 operational NSCs (4 ENBS, 2 6-test)				
	Setting up of continuity clinics and referral system in the provinces to further strengthen the referral and management network of positive cases in the hope that no patient will be deprived of long term care.	14 Continuity Clinic Exists				
	Strict enforcement of newborn screening policies to ensure delivery of sustainable ENBS service at the national level down to local level.					
	Enhancement of diagnosis, follow up, and management of confirmed cases through prompt recall and confirmatory tests of patients by effective utilization of service delivery network for appropriate referral and management of patients, collaborative partnerships and assessment of recall and follow up protocols.					
	Train and deploy clinical geneticists, pediatric endocrinologists and genetic counselors at the provincial level.					

	Develop human resource complement at the DOH and Local Government Units (LGUs) to ensure that nurses, doctors and other health professionals working in the continuity clinics and regional offices are given plantilla positions.					
Enhancing Health Promotion and Advocacy	Develop an ENBS national communication plan to increase the uptake of ENBS nationwide.					
	Strengthen alliance building with different organizations and Local Government Units (LGUs).					
	Integrate ENBS in the academic curriculum with other health related subjects in the secondary and tertiary levels, specifically in Grade 8 level.	Integration of ENBS in Gr 8 Curriculum on-going				
	Intensify training and development of innovative training materials for newborn screening with post training evaluation.					
Optimizing Health Information Management Systems for Expanded Newborn Screening	Establish efficient national database and case registries for real-time generation of data.					
	Develop and implement online monitoring system for easy access of data.					
Strengthen Monitoring and Evaluation Establishing Sustainable Financing scheme	Modify NBS evaluation tools such as the Philippine Performance Evaluation Assessment System (PPEAS) tools for NSCs, ROs, Continuity Clinics and NSFs for periodic assessment.					
	Conduct program review, audit and evaluation procedures and systems for both laboratory and administrative units.					
	Establish local QA laboratory for the monitoring and evaluation of Newborn Screening Centers (NSCs).					
Establishing Sustainable Financing scheme	Include full coverage of ENBS in the Philhealth newborn care package.	Ongoing				
	Provide funds for research grants for policy recommendation on NBS.					

	<p>Building alliance with LGUs and other institutions/agencies to allot budget for screening, confirmatory tests and management in the continuity clinics by having a community financing schemes and programs.</p>					
	<p>Continuous collaboration to include NBS program in the Department of Health investment plan and allot budget for the needs of newborn screening from the national fund including health promotion and communication campaign at all levels using different media platforms.</p>					