Manual of Operations

National Comprehensive Newborn Screening System

REVISED EDITION 2023

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Department of Health
University of the Philippines Manila - National Institutes of Health

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April
2023

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PREFACE

The first Newborn Screening Manual of Operations was prepared in 1996 by the original set of newborn screening coordinators. It covered advocacy, sample collection and submission, recall of patients and referral to the corresponding specialists for management. There were several editions from 1996 to 2004. With the passage of Republic Act 9288 or the Newborn Screening Act or 2004, a more comprehensive Newborn Screening Manual of Operations was published in 2004 as the definitive book on newborn screening implementation.

In the fifteen years of implementation of the law, the newborn screening program has continually offered quality services to Filipino newborns. All changes in the program implementation are integrated in this revised edition including expanded newborn screening. The reconfigured 2016-2025 Strategic Plan of the Department of Health (DOH) and 2017 – 2030 Strategic Framework have been incorporated in this manual.

This revised edition serves as a working guide to newborn screening implementation. It provides program implementers in the national, regional and local level the answers to the following questions:

- How does one implement newborn screening and make it work smoothly?
- How do we ensure that NBS is done properly and promptly in all regions of the Philippines?
- How do we make supplies available in a timely and efficient manner?

- How can we provide better management for positive screens, recall, confirmatory tests, and referral to specialists?
- How and when do we do evaluation and monitoring of newborn screening at NBS facilities?
- How can we ensure quality implementation of newborn screening nationwide?

NEW TO THIS EDITION are the following topics:

- Panel of expanded newborn screening with fact sheets;
- Guideline on the management of patients found positive in any of the disorders in the newborn screening panel to ensure that they live to grow normally;
- Long term follow-up and the role of the NBS continuity clinics;
- Section on the storage, retention and usage of dried blood spots is also included; and
- Special considerations: sick, premature and low birth weight.

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INTRODUCTION

Brief History of Newborn Screening in the Philippines

Newborn screening (NBS) is an essential public health strategy that enables the early detection and management of several congenital metabolic disorders, which if left untreated, may lead to mental retardation and/or death. It has been an integral part of routine newborn care in most developed countries for decades, either as a health directive or mandated by law. Early diagnosis and treatment of the disorders can result in normal growth and development of the affected individual.

NBS in the Philippines began in 1996, when a group of pediatricians and obstetricians initiated the Philippine Newborn Screening Project in 24 pilot hospitals in Metro Manila. The group conducted the research with the following objectives: a) to determine the local incidence of congenital hypothyroidism (CH), congenital adrenal hyperplasia (CAH), phenylketonuria (PKU), galactosemia (Gal) and homocystinuria (HCY); and b) to make recommendations for nationwide implementation of newborn screening. In aid of the study, samples were sent daily from June 1996 to the Newborn Screening Laboratory of New South Wales, Australia up until the establishment of a laboratory in September 1997 at the National Institutes of Health, University of the Philippines Manila, which is now known as NSCNIH.

The study results showed the following incidences: CH-1:3,839, CAH-1:9,485, PKU-1:53,748, GAL-1:80,622. Since no case of HCY was detected, it was replaced with Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency in the NBS panel of disorders in 2000. Given these data, the group recommended to the Department of Health (DOH) the adoption of NBS as one of the priority programs for newborn care and to work for the nationwide implementation of the screening program.

In 1999, in accordance with its mandate and thrust of ensuring quality of life for all Filipinos, DOH included newborn screening in their Child Health 2025 framework. An inter-agency task force was created to design a plan for the nationwide implementation of NBS. Representatives from different regions were designated as regional coordinators and trained in September 1999 to disseminate and initiate NBS at the regional level.

In January 2000, DOH issued Administrative Order 1-A s 2000 entitled "Policies on the Nationwide Implementation of Newborn Screening" (see *Annex 1)*. It outlined the guidelines for the implementation of NBS. In February 2001, the DOH created an inter-agency National Technical Working Group on Newborn Screening (NTWG-NBS). The group was tasked to provide national direction and guidance in the attainment of the project goals stipulated in the DOH Administrative Order 1-A s 2000.

In June 2001, a strategic planning workshop on NBS was conducted and participated in by representatives from selected DOH-Centers for Health Development (DOH-CHDs), NBS implementers of participating institutions (private hospitals, DOH-retained hospitals, Rural Health Units [RHUs] and LGU Hospitals) and some stakeholders.

As part of the advocacy strategy, in January 2004 Presidential Proclamation No. 540 (see *Annex 2)* was issued declaring the 1st week of October of each year as "National Newborn Screening Awareness Week."

Despite extensive efforts by both the government and private sectors, the coverage of screened newborns remained low at 3% of the newborn population. In April 7, 2004, Republic Act 9288 otherwise known as the Newborn Screening Act of 2004 was enacted to institutionalize NBS in the country. It established a National Comprehensive Newborn Screening System (NCNBSS) to ensure an integrative and sustainable implementation of the NBS. See *Annex 3: Republic Act 9288*.

The Implementing Rules and Regulation of RA 9288 was signed in October 5, 2004 along with the Memorandum of Agreement between the DOH and the National Institutes of Health (NIH) for the creation of the Newborn Screening

Reference Center (NSRC). The NSRC was envisioned to provide technical assistance to the DOH in implementing NBS in the country.

Since the passage of the law and the signing of the IRR, several policy developments supported the successful implementation of RA 9288. See *Annex 4: Implementing Rules and Regulation of RA 9288.*

2006

- Inclusion of NBS in the DOH licensing requirement for health facilities.
- Inclusion of NBS as part of the *Newborn Care Package* of Philippine Health Insurance Corporation (PhilHealth) covering 90 percent of the fee in December 2006 and increased to 100 percent in September 2011. *See Annex 5 on Philhealth Circulars from 2006 - 2011.*

- Establishment and accreditation of Newborn Screening Center (NSC) West Visayas State University Medical Center equipped with a NBS laboratory and recall/follow up program.

2007

- Offering of scholarships for fellowship in Clinical Genetics and Pediatric Endocrinology.

2008

- Appointment of Expert Committees that would regularly participate in the review of datasets, cut-offs, treatment and management protocols of the different NBS disorders among others.

2009

- Establishment and accreditation of Newborn Screening Center (NSC) Southern Philippines Medical Center for NSC-Mindanao.

- Participation in External Quality Assurance (EQA) Program for the G6PD Deficiency Confirmatory test was established in partnership with the International QA Program of Preventive Medicine Foundation in Taiwan. This is in addition to the existing external quality control and proficiency testing for thyroid stimulating hormone (TSH), 21 – α-hydroxylase (17OHP), total galactose, phenylalanine (PHE), which is in

collaboration with the Center for Disease Prevention and Control (CDC) in Atlanta, Georgia. EQA for Leu was included in 2012.

- Setting up of confirmatory testing centers for G6PD Deficiency. Tertiary hospitals were identified in the different parts of the Philippines which were equipped and were willing to integrate G6PD enzyme assay as one of their services. By the end of 2018, there are 26 G6PD Confirmatory Centers in the country. Confirmatory reference laboratories for the other disorders such as the metabolic and hemoglobinopathies were identified in 2014.

2010

- Establishment and accreditation of Newborn Screening Center (NSC) Angeles University Foundation Medical Center for NSC-Central Luzon.

2011

- Offering of scholarships for Genetic Counselors

2012

- Inclusion of Maple Syrup Urine Disease (MSUD) in the NBS panel with the approval by the Advisory Committee on Newborn Screening (ACNBS).

2013

- Establishment and accreditation of Newborn Screening Center (NSC) Daniel O Mercado Medical Center for NSC-Southern Luzon.

2014

- Establishment of regional NBS Continuity Clinics (NBSCCs) for long term follow-up of patients with confirmed diagnosis in different regions in the country with 14 clinics by end of 2015.
- Offering of expanded newborn screening (ENBS) by December 2014 increasing the NBS panel from 6 to more than 28 conditions.

2017

- Establishment and accreditation of Newborn Screening Center (NSC) Mariano Marcos Memorial Medical Center for NSC-Northern Luzon.

2018

- Addition of argininosuccinic aciduria (ASA) with the approval by the Advisory Committee on Newborn Screening (ACNBS) upon the recommendation of the DOH National Technical Working Group on Newborn Screening (DOH NTWG-NBS)

2019

- PhilHealth coverage of ENBS under the Newborn Care Package effective January 5, 2019 as guided by PhilHealth Circular No. 2018-0021 (see *Annex 6*).
- Full implementation of ENBS where all infants born in accredited facilities shall be tested in ENBS only beginning May 1, 2019 as guided by Administrative Order 2014-0045-A (see *Annex 7*).

2020

- Inclusion of Center for Human Genetics Services in the Revised Guidelines on the Implementation of the Expanded Newborn Screening (*See Annex 8).*
- Establishment and accreditation of Newborn Screening Center (NSC) Eversley Child Sanitarium and General Hospital for NSC-Central Visayas.

See *Annex 9: NBS Milestones 1996-2020*

Vision, Mission, Goal and Strategic Directions

Vision

The National Comprehensive Newborn Screening System shares the vision of the Child 2025 Planning Framework aiming that by 2025, every Filipino child will be:

- Born healthy and well, with an inherent right to life, endowed with human dignity; and

- Reaching her/his full potential with the right opportunities and accessible resources.

Mission

To ensure that all Filipino children will have access to and will avail of total quality care for the optimal growth and development of their full potential.

Goal

By year 2025, all Filipino newborns are screened for the more common and life-threatening congenital endocrine and metabolic disorders.

Strategic Directions [1]

The implementation of NBS is phased, ensuring a balance of activities in each of the six (6) elements of the NBS system, namely: (a) health facility involvement; (b) operations, systems development, networking; (c) service delivery package; (d) advocacy; (e) finance; (f) promotions.

Phase 1: Foundation Laying and Accelerated Implementation

This phase focused on developing model hospitals and RHUs, alliance building, national policy and legislation, capacity/capability-building, and creating the supportive environment to pave the way for smooth implementation of the program. This phase signalled the start of tri-media promotion to increase awareness and demand for NBS; and mainstream of all elements of the NBS system through integration into the existing maternal and child health service package.

[1] A new strategic direction was released on 2017. See Figure 1.

Phase 2: Expansion

This phase ensured involvement of all DOH Retained Hospitals, RHUs and birthing homes; increase capacity by establishing more screening laboratories and confirmatory laboratories and integrating newborn screening in health education.

Phase 3: Expansion and Sustained Implementation

With sustained promotion, NBS was offered to all other birthing homes and lying-ins. To monitor long term outcome of patients, this phase ensures availability of services of specialists to include geneticists, pediatric endocrinologists, and genetic counselors. Strengthening of Treatment Network will also be a focus on this phase.

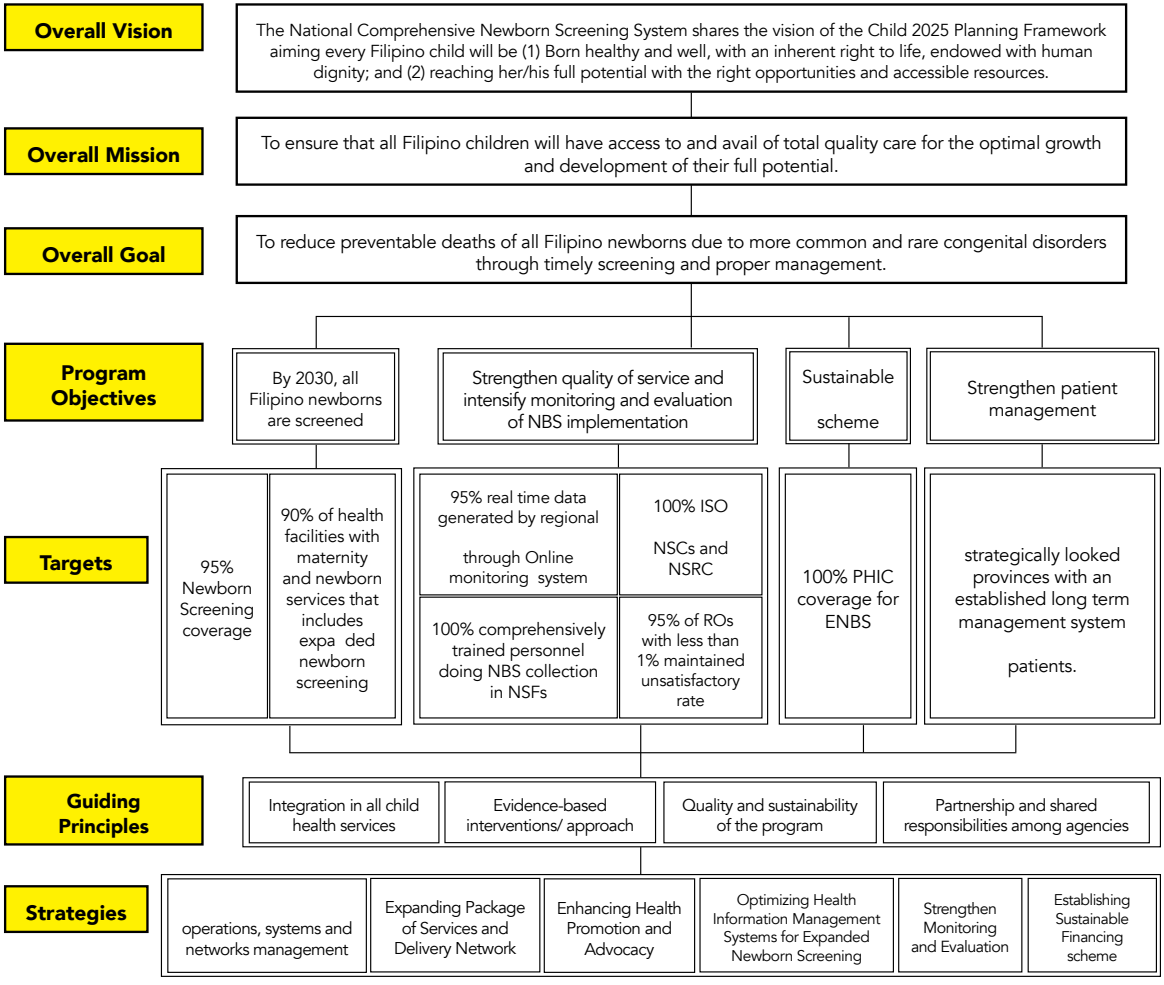


Figure 1. The National Comprehensive Newborn Screening System Strategic Direction.

The DOH strategic framework ending 2030 was released in 2018. See *Annex 10: AO No. 2018 – 0025 National Policy and Strategic Framework for ENBS for 2017 – 2030.*

Chapter 1

Managing Newborn Screening at Various Levels

Organizational Framework

The DOH is the lead agency, providing the overall direction and guidelines for implementing the NCNBSS at the national and local level. The National Institutes of Health- University of the Philippines, Manila, as a partner, serves as the technical arm. A multi-sectoral advisory committee ensures a participative decision making for the smooth flow of NBS operations.

As stipulated in RA 9288, the ACNBS is created to ensure sustained inter-agency collaboration. It is the advisory body to the Office of the Secretary of the DOH in terms of policy and program directions. It reviews and approves recommendations of the NTWG-NBS.

National Level

The prime responsibility of the national level institutions is to ensure that appropriate policies, standards, logistics and technical assistance are available to all implementing units. The structure and operations at the national level must be supportive and responsive to the ever-changing demands of service delivery at each peripheral unit. See *Annex 11: NCNBSS Functional Chart.* The following institutions/units and bodies are the primary movers:

A. Disease Prevention and Control Bureau (DPCB)

The DPCB through its Child, Adolescent, and Maternal Health Division oversees the operations and nationwide implementation of the NCNBSS. It has the following functions:

1. Serves as the lead office for the newborn screening program and coordinates activities and programs in pursuit of the objectives of DOH. It spearheads the continuous organization of the NTWG on NBS until such group has fully implemented and institutionalized all the necessary components of the NCNBSS;
2. Provides technical assistance to DOH-CHDs/Ministry of Health Bangsamoro Autonomous Region of Muslim Mindanao (MOH-BARMM) relative to NBSs and establishes coordination with

other stakeholders in planning, development of materials, monitoring and evaluation for NBS;
3. Provides venues for developing innovative approaches and models of implementation in partnership with other cooperating agencies;
4. Advocates for the adoption of NBS among public and private institutions and practitioners;
5. Monitors and evaluates the field implementation of NBS; and
6. Chairs the NTWG-NBS.

B. National Technical Working Group Newborn Screening (NTWG-NBS)

The main role of this body is to set the goals of the program for long and medium term target setting and planning. It ensures that all policies, guidelines, and standards of the program adhere to overall internationally accepted standards and ethical considerations. Specifically, it has the following functions:

1. Develops/reviews policies, standards, and guidelines on NBS for recommendations and approval of the ACNBS;
2. Recommends the disorders to be included in the NBS panel;
3. Reviews and recommends the NBS fee to be charged by the NSC;
4. Develops/reviews strategies and tools that ensure effective and efficient implementation of NBS at various levels;
5. Formulates national program/project plan, proposals, and collaborative studies on NBS;
6. Reviews the report of the NSRC on the performance of the NSCs and recommend corrective measures as deemed necessary; and
7. Meets quarterly or may schedule supplementary meetings depending on the demand of the tasks. The Health Secretary, through a DOH issuance, appoints its members, as selected and recommended by DCPB and NIH.

C. National Institutes of Health (NIH)

NIH, under the University of the Philippines Manila, serves as the technical partner of DOH in ensuring the quality of service and sustainability of the NCNBSS. It performs this function through the NSRC.

D. Newborn Screening Reference Center (NSRC)

The NSRC is the central facility based at the NIH and acts as the secretariat of the ACNBS. It has the following specific functions:

1. Responsible for training, technical assistance, and continuing education for laboratory staff in all NSCs. It acts as the principal repository of technical information relating to standards and practices. It assists in training activities in all aspects of the NBS program. It oversees the content of educational materials in coordination and approval from the DOH Health Promotion and Communication Services (DOH HPCS);
2. Defines the testing and follow-up protocols for NSCs;
3. Maintains an external laboratory proficiency-testing and certification program;
4. Oversees the national testing database and case registries. It submits reports semi-annually or more frequently as the need arises to the ACNBS and to the DOH on the status of and relevant health information derived from the database. It shall also prepare a plan for long-term outcome evaluation of NBS utilizing the case registries;
5. Reports to the DOH the NSCs found violating the Implementing Rules and Regulations of RA 9288 and those performing and providing NBS procedures and services without any DOH Accreditation;
6. Recommends the establishment of NSCs. Participates in consultation and evaluation activities initiated by Health Facility and Services Regulatory Bureau (HFSRB) in relation to the NSRC and the NSCs performance and in improving implementation of the IRR of RA 9288;

7. Collects from the NSCs the monthly 4% of the NBS fees earmarked for DOH-CHDs or its future equivalent and transfers the said portion; and
8. Observes strictly the compliance of newborn screening facilities (NSFs) to quality standard NBS procedures.

For the purpose of program evaluation and monitoring, the NSRC maintains a database of all patients tested, and a registry for each condition that is submitted to DOH annually.

In terms of implementation of the NBSCCs, it has the following specific functions:

1. Oversees the implementation of activities of newborn screening continuity clinics and birth defects continuity clinics;
2. Secures monthly, quarterly, and yearly reports from participating units and ensure their timely dissemination to various program stakeholders;
3. Participates in consultation and evaluation activities initiated by the DOH in relation to the NBSCCs and birth defects continuity clinics' performance and in improving of rules and regulations; and
4. Assists in the training activities of the program.

E. Epidemiology Bureau (EB)

The EB, in collaboration with the regional/ provincial epidemiology units, is responsible for developing a surveillance system for heritable conditions. It establishes a registry of cases linked with the NIH as the central registry center, and the RHUs as the base registry units.

F. Health Facilities Services and Regulatory Bureau (HFSRB)

The HFSRB, in collaboration with NIH, is responsible for regulating health facilities performing NBS procedures through:

1. Inclusion in the licensing/licensing renewal requirements for hospitals and birthing facilities;

2. Accreditation procedures and monitoring for compliance and quality assurance;
3. Development of needed rules and regulations pertaining to the regulation of the same; and
4. Monitoring and evaluation of the NSCs.

G. Health Facility Development Bureau (HFDB)

The HFDB participates in providing technical assistance and leadership for the continuous effective and efficient implementation of NBS in hospitals. This is done in coordination with the DOH-CHDs/MOH BARMM. It also encourages, hospitals to participate in the monitoring, research and development efforts that will be pursued and initiated by concerned stakeholders and the NIH.

H. Health Promotion and Communication Service (HPCS)

The HPCS acts as the lead office in the promotion of NBS and develops advocacy materials for dissemination to all partner agencies (LGUs, academe, NGOs) and stakeholders. All IEC materials and collaterals will be screened and reviewed by HPCS.

I. NIH - Institute of Human Genetics (NIH-IHG)/ Center for Human Genetics Services (CHGS)

The NIH-IHG, specifically the Clinical Genetics and Research Unit, and Center for Human Genetics Services (CHGS), provides comprehensive clinical evaluation and laboratory diagnostic services to families or individuals with or at risk of inheritable disease. It also provides support for the Telegenetics Referral System and the Birth Defects Surveillance System in the country. The CHGS is present in Luzon, Visayas, and Mindanao. It is tasked with the following functions in terms of implementation of the NBSCCs:

1. Establishes an efficient system in the procurement and availability of medicines, medical food, and other medical requisites needed in the management of patients confirmed with conditions detected through newborn screening;
2. Provides subspecialist (genetics, endocrinology) expertise and technical support for the operations of Telegenetics Referral System;

3. Strengthens the surveillance program for newborns with birth defects in the country; and
4. Establishes systems for the referral of patients with birth defects from BDS health facility to NBSCCs and Birth Defects Continuity Clinics.

J. Department of the Interior and Local Government (DILG)

The DILG is one of the major stakeholders of the NCNBSS. It has the following functions:

1. Encourages LGUs to implement RA 9288 and extend total cooperation in the implementation of the said law; and
2. Assists the DOH in the monitoring and evaluation of the program.

K. Council for the Welfare of Children (CWC)

CWC is one of the major stakeholders of the NCNBSS. It has the following functions:

1. Integrates NBS in the establishment of the system for early identification, prevention, referral and intervention of developmental disorders and disabilities in early childhood; and
2. Provides avenues in developing innovative advocacy and communication approaches in partnership with civil societies, NGOs and other groups.

L. Philippine Health Insurance Corporation (PhilHealth)

PhilHealth is responsible for including NBS services in its benefit package for its members.

Regional Level

The main role of the DOH-CHDs/MOH BARMM is to act as facilitators and collaborators to enable participating units such as lying-in, birthing homes,

health centers, and government and private hospitals to fully implement the program at the local level.

The following are the specific functions of the DOH-CHDs/MOH BARMM:

1. Establishes an NBS Program at the DOH-CHDs/ MOH BARMM, through the hiring of a licensed nurse and/or medical staff, to address problems and issues encountered in the daily implementation of the program;
2. Organizes/Conducts trainings and orientations to ensure continuous recruitment and updating of NSFs and provide NBS educational materials to participating units and the general public;
3. Conducts awareness and advocacy campaign about newborn screening including development of local IECs;
4. Collaborates with various stakeholders in the implementation of newborn screening including LGUs, specialty societies, academe, and other partners and government offices;
5. Monitors NBS implementation in NSFs. Strictly observes the compliance of NSFs to quality standard NBS procedures;
6. Secures monthly reports from NSFs and ensure their timely dissemination to various program coordinators, DPCB and NSRC;
7. Meets the coordinators of the various participating units to thresh out problems and issues;
8. Establishes a mechanism for recall of patients with a positive screen; and for referral of these patients to experts for management and follow-up care;
9. Identifies and sustains a treatment and referral network in the region to ensure capable management of identified positive cases by a nurse or genetic counsellor and a duly licensed physician or a medical specialist such as but not limited to a neonatologist, a pediatric endocrinologist and a clinical geneticist;
10. Receives, manages, and disburses the 4% earmarked amount for the purpose of implementing the newborn screening program and facilitating achievement of required outputs as provided in the AO No. 2013-0015 *(See Annex 12: Guidelines on the Newborn Screening DOH CHD and MOH BARMM 4% Fund Utilization)*; and
11. Assists in the operations of the NBSCCs through, but not limited to, recall of confirmed patients for referral to experts for management and follow-up care; and 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 depending upon the availability of funds.

Local Level

The local level refers to health facilities under the local government units (LGUs). Local Chief Executives and their local health officials:

1. Develops local ordinances in support of the newborn screening program;
2. Ensures that adequate and sustained NBS services such as information, education, communication, screening, recall and follow-up are being provided in all LGU health facilities (RHU/ City Health Unit, Lying-ins, City/Municipal/ District/ Provincial Hospitals);
3. Establishes a functional case management referral system with strategically accessible tertiary care hospitals;
4. Establishes coordination and networking among concerned agencies;
5. Monitors and evaluate the NBS implementation in their localities; and
6. Establishes and provides–financial packages to make NBS accessible particularly among the economically deprived populace.

Newborn Screening Center (NSC)

The NSC is a facility equipped with a newborn screening laboratory that complies with the established standards. The NSC provides all required laboratory tests, and has an immediate recall and short-term follow-up program for newborns with positive screen for heritable conditions.

It also provides roster of confirmed patients, including their protocols for management and list of follow-up laboratory procedures, to the NBSCC.

Newborn Screening Facility (NSF)

Newborn Screening Facility (NSF) is defined as any health facility that offers NBS services to infants, born either in the facility, its catchment area or elsewhere, and has operational recall/follow-up system for newborns with heritable conditions.

The NSF may be any health facility with maternity services, birthing homes, lying-in clinics or outpatient clinics such as RHUs and health centers. To be included in the network, a health facility must apply and complete the institutional database form *(see Annex 13)* and all documentary requirements. The following are the major responsibilities of NSFs:

1. Organizes an NBS team that will oversee the implementation of the program and serve as linkage with the NSC and respective DOH-CHDs/MOH BARMM; the NBS team will be chaired by an Overall NBS Coordinator and assisted by at least one (1) Assistant NBS Coordinator who will oversee the NBS process, collection of samples, release of results, prompt recall, and follow up of positive cases;
2. Establishes a system for collection of NBS samples from all newborns that come to the facility, with a target coverage of 100%;
3. Submits monthly live births to the respective DOH-CHDs/ MOH BARMM indicating total number of newborns seen at the facility, number of NBS performed, and list/status of positive cases identified;
4. Organizes health education activities to inform parents and clients of the importance of NBS;
5. Ensures recall and proper management of patients with positive screens. If the facility does not have trained practitioners, it is their responsibility to refer the patient to other facilities with trained practitioners or experts who can manage congenital metabolic disorders;
6. Releases NBS results to attending practitioners, or directly to parents if the attending practitioner is unavailable; and
7. Monitors and evaluates the implementation of NBS within the institution. For RHUs, include barangay health workers in the monitoring.

Newborn Screening Team

The NBS Team is crucial to the effective and systematic implementation of NBS in the NSF. It is important that each health facility organizes its own NBS team.

A. Steps in Organizing the Newborn Screening Team

1. Organize the NBS team by identifying key individuals who will ensure successful newborn screening in the health facility.

2. Identify the Overall NBS Coordinator and Assistant Coordinator/s in the facility.
3. Assign specific tasks to key persons/staff members.
4. Formulate an action plan to include resource requirements, time frame, targets, and indicators for success of the NBS in the catchment area.

B. Duties and Responsibilities of the NBS Team

The NBS team must ensure proper and efficient implementation of NBS. The NBS team should delegate tasks to identified key persons and set standards and guidelines for each. A sample task list is provided below:

1. Supplies disbursement
2. Staff training
3. Advocacy/promotion of NBS
4. Collection and sending of samples
5. Release of NBS results and recall of patients for retest
6. Recall of positive screens/referral/follow-up of confirmed patients
7. Documentation and reporting of confirmatory results to NSC
8. Financial concerns
9. Submission of reports (i.e. census)

Newborn Screening Continuity Clinic (NBSCC)

The NBSCC refers to an ambulatory clinic based in a tertiary hospital identified by the DOH to be part of the NCNBSS Treatment Network. It is equipped to facilitate continuity of care of confirmed patients in its area of coverage.

Host Facilities – Continuity Clinic

This tertiary hospital, referred to as the host facility, is equipped to facilitate continuity of care of confirmed patients in its area of coverage.

In terms of implementation of the NBSCC, it has the following specific functions:

1. Sets-up newborn screening continuity clinic and Birth Defects Continuity Clinic;

2. Oversees the selection and hiring of personnel for the NBSCC in their facility through the Chair of Department of Pediatrics;
3. Provides clinic space for patient consultation and workstation for the follow-up nurse;
4. Assures the best possible outcome for individuals with disorders identified through newborn screening by providing long-term follow-up treatment and management to all confirmed positive patients in their assigned region/s;
5. Attends to patients with birth defects for long-term care and management;
6. Integrates the NBSCC to the current services of the host facility; and
7. Ensures the sustained operation of the NBSCC and Birth Defects Continuity Clinic, according to the Operational Guidelines set by the DOH and the NSRC for NBSCC.

Chapter 2

Steps in Implementing Newborn Screening

Implementing NBS involves the different steps in the practice of NBS from motivation of parents to the management of patients:

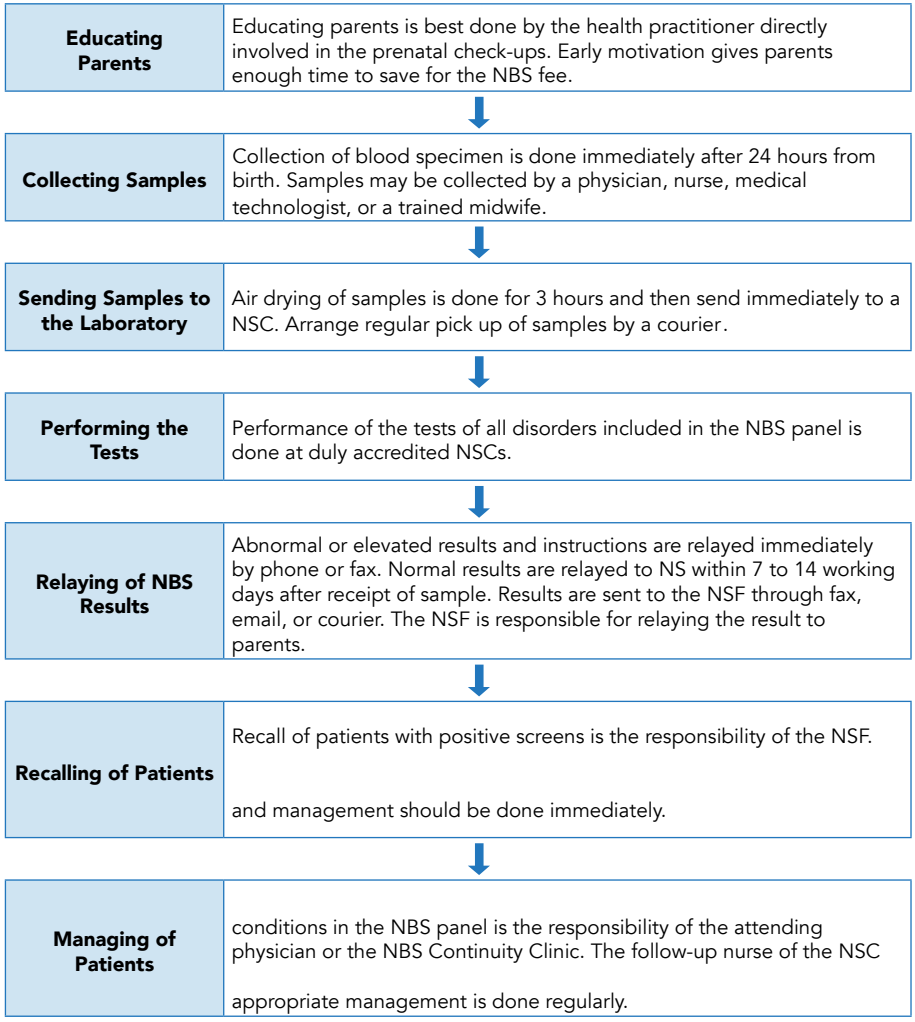


Figure 2. Flowchart of newborn screening activities.

The basic system and processes for ensuring successful newborn screening is shown in Figure 3 below. Details of each step are discussed in the succeeding pages.

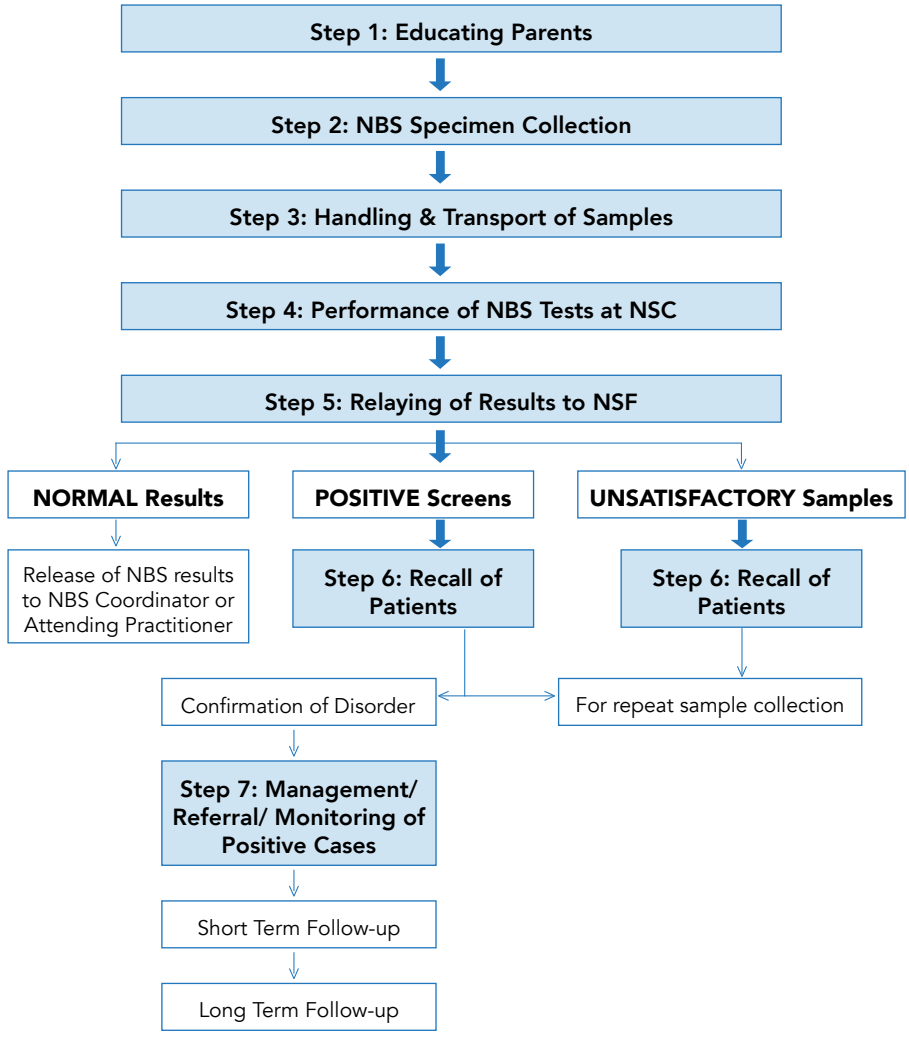


Figure 3. Newborn screening flow of implementation.

Educating Parents

Education of parents is essential for the successful implementation of NBS. Proper and early education of parents about NBS and its benefits will help parents understand NBS and motivate them to have their baby screened.

All health workers who provide prenatal care and assist in the actual delivery of a baby are responsible for informing parents about newborn screening.

Education of parents may begin from the time the parents plan to have children to the time the baby is delivered. Venues include:

- Pre-marriage Counseling Sessions
- Mother's classes
- Prenatal Visits
- Home Visits

The following issues must be discussed: *(see Annex 14: FAQ on Newborn Screening)*

- What is NBS? What disorders are being screened?
- Why is NBS important? What are the benefits to the newborn?
- How is NBS performed?
- Cost of NBS

The earlier parents are informed of the benefits of newborn screening, the greater the chance of NBS being performed.

What if parents refused to have their baby screened?

Parents may only refuse testing due to religious belief. This must be accompanied with a written refusal form *(see Annex 15)*. This document should be filed with the baby's medical record at the NSF.

Collecting the Specimen

It is important to strictly follow the procedure for dried blood spot (DBS) sampling because proper specimen collection ensures accurate results. Care must be taken in order to prevent contamination.

Personnel who can collect blood sample for NBS

Any trained health worker such as physicians, medical technologists, nurses, and midwives may collect blood specimens for NBS.

Best/Ideal Time for NBS sample collection

Sample must be collected immediately after 24 hours from birth before sending the mother home.

- Sample collection done before the ideal time may result either false positive or false negative screen.
- NBS samples taken less than 24 hours of life will require urgent repeat sample collection
- For infants that are SICK, PRETERM, and with LOW BIRTH WEIGHT, (*see page 37)*

Place to collect the sample

Any clean/dry/secured place can be designated for sample collection.

Filling out the Newborn Screening Filter Card

A. Accomplish the NBS filter card properly

- Avoid contamination
- Prevent mislabelling
- Ensure **COMPLETE** and **ACCURATE** data. Incomplete data leads to the DELAY in interpretation and release of results. WRITE CLEARLY AND LEGIBLY. AVOID ERASURES. Data erasures might cause information to be invalid.

General Guidelines in filling out the NBS Filter Card

1. Make sure that hands are clean and dry before handling the filter card. Do not put oil or hand lotion as this can cause contamination on the card.
2. Fill out the NBS Filter Card with the correct information. Use a ballpoint pen with black or blue ink. Do not use water soluble ink pens because these may run and contaminate the sample. Avoid touching the specimen collection portion of the filter card.
3. Do not insert the filter card in the patient's chart to avoid contamination of the filter card.
4. Fill out all items legibly and completely. Use BLOCK LETTERS and leave a space (_) between each word. Each box corresponds to only one letter or number. If the boxes provided are not enough to accommodate the whole name, fill in the information until the last available box.

The information requested for on the filter card is important in the interpretation of results. It is essential that the card be filled out completely.

Important Reminders

- ☐ Do not write anything in the pink-shaded portion/box of the NBS Filter Card labelled FOR LABORATORY USE ONLY.
- ☐ Complete all information requested.
- ☐ Write legibly.
- ☐ Check the NBS Filter Card for accuracy of information and completeness of data.
- ☐ Perforated portion indicating *"Detach for Philhealth Use"* must be attached to the Philhealth claim form.

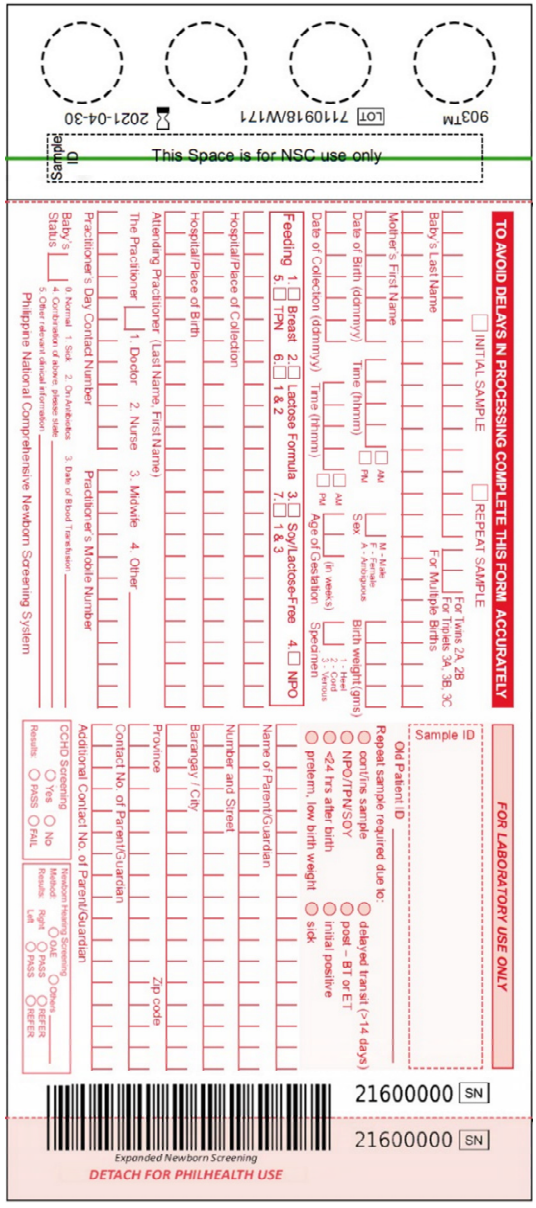


Figure 4. The newborn screening filter card.

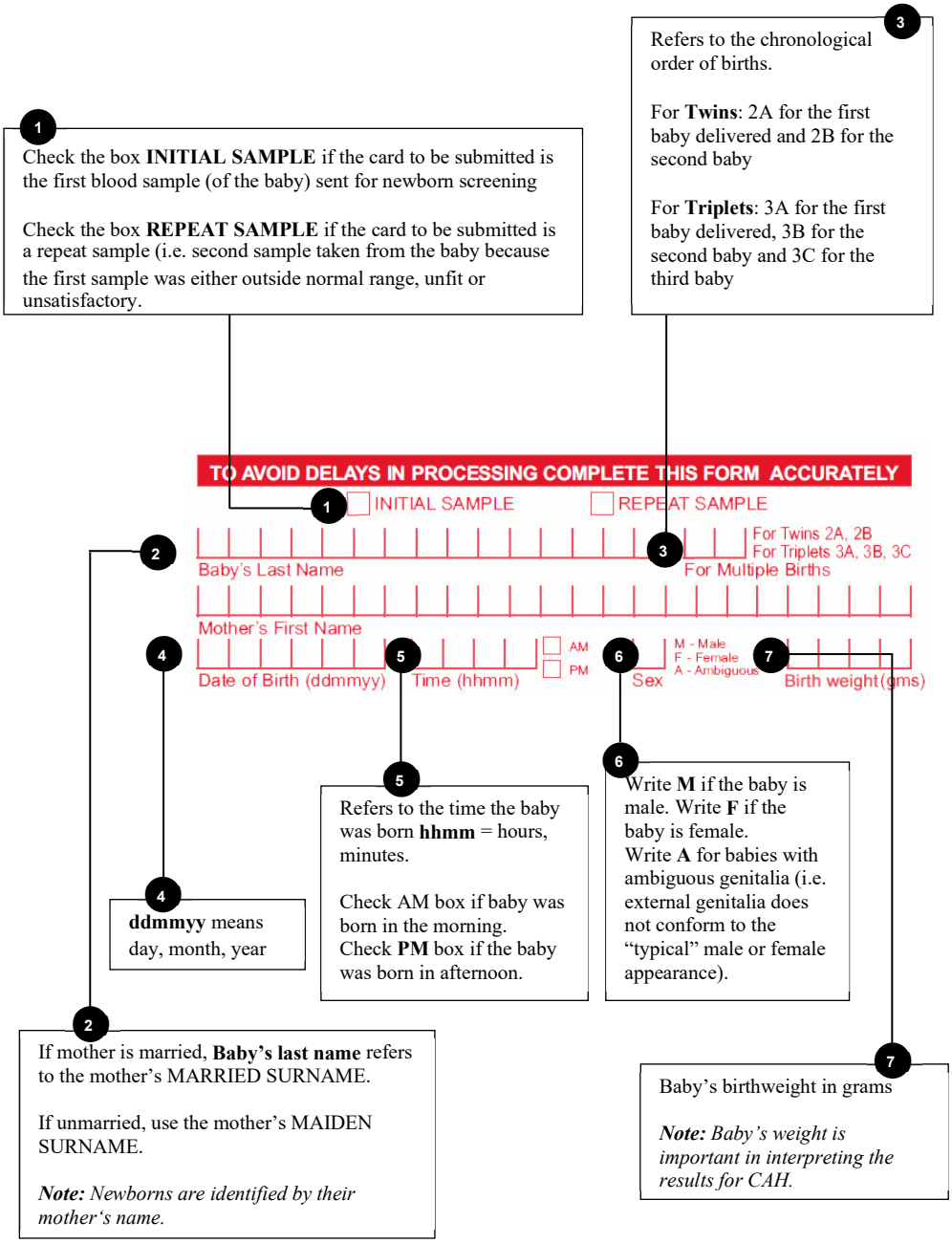


Figure 4.2 Accomplishing the newborn screening filter card: baby's information.

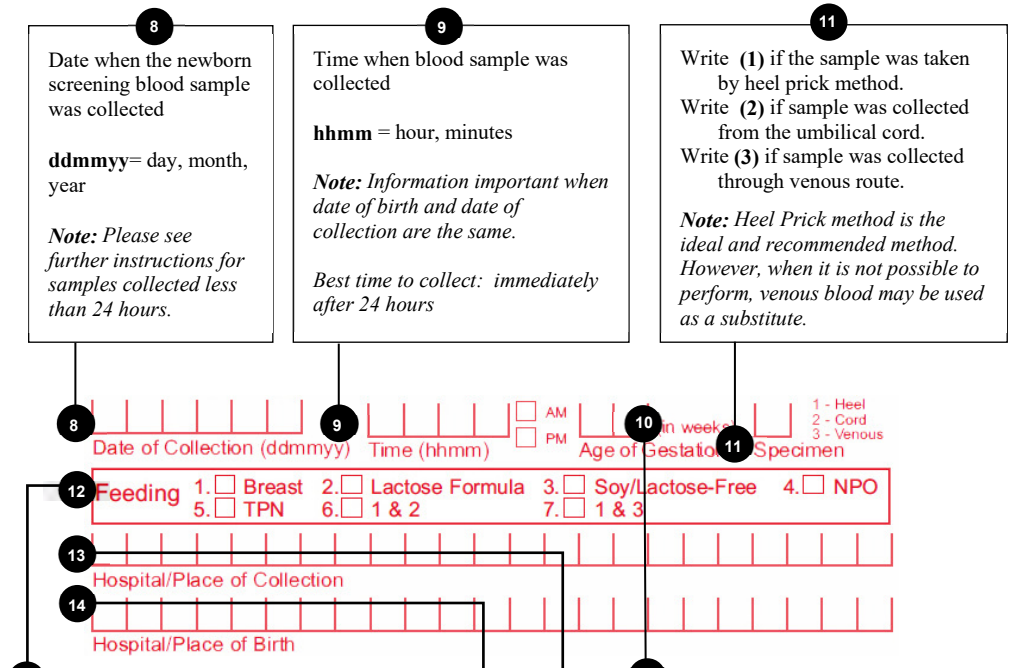


Figure 4.3 Accomplishing the newborn screening filter card: hospital information.

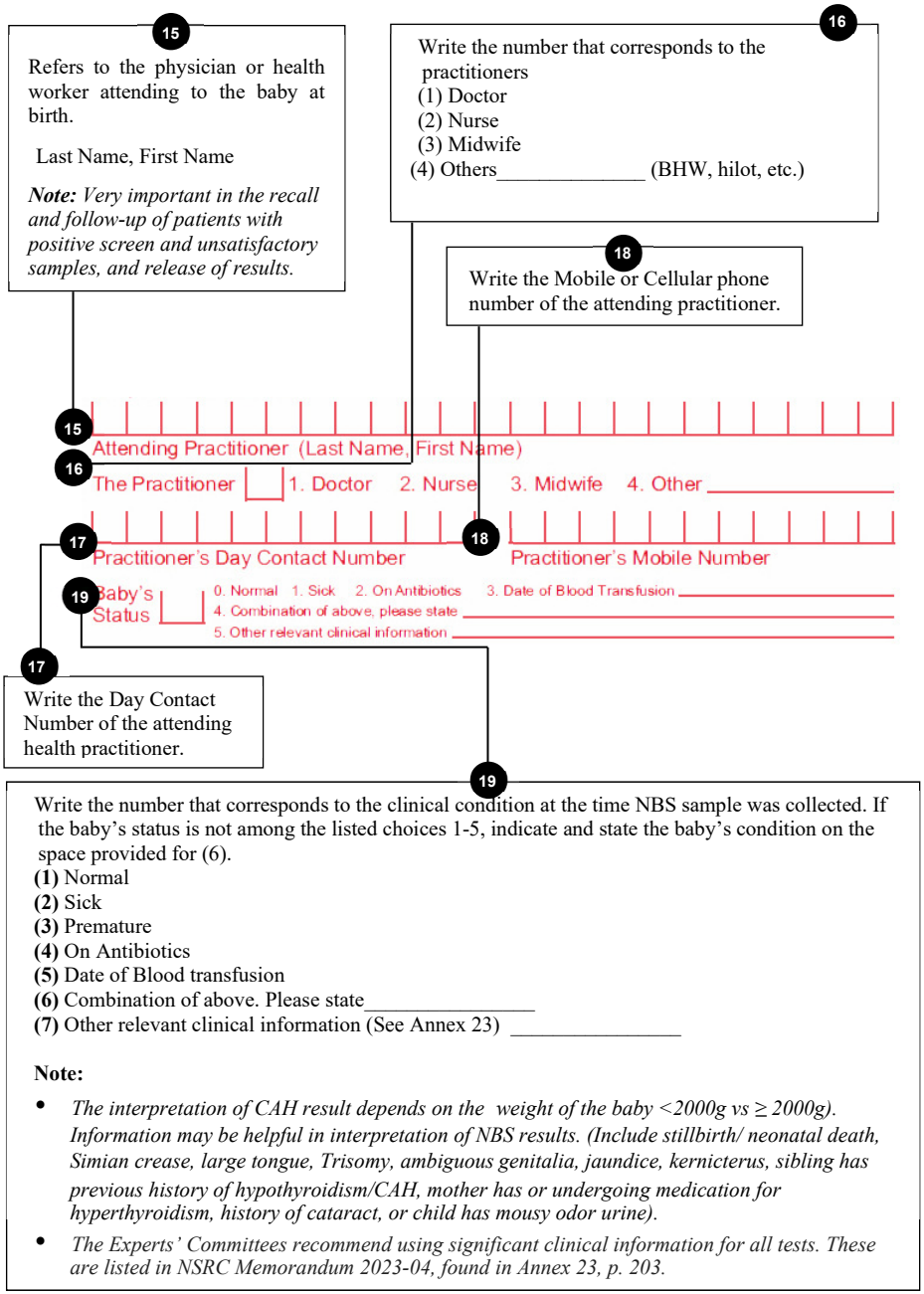


Figure 4.4 Accomplishing the newborn screening filter card: practitioner's information

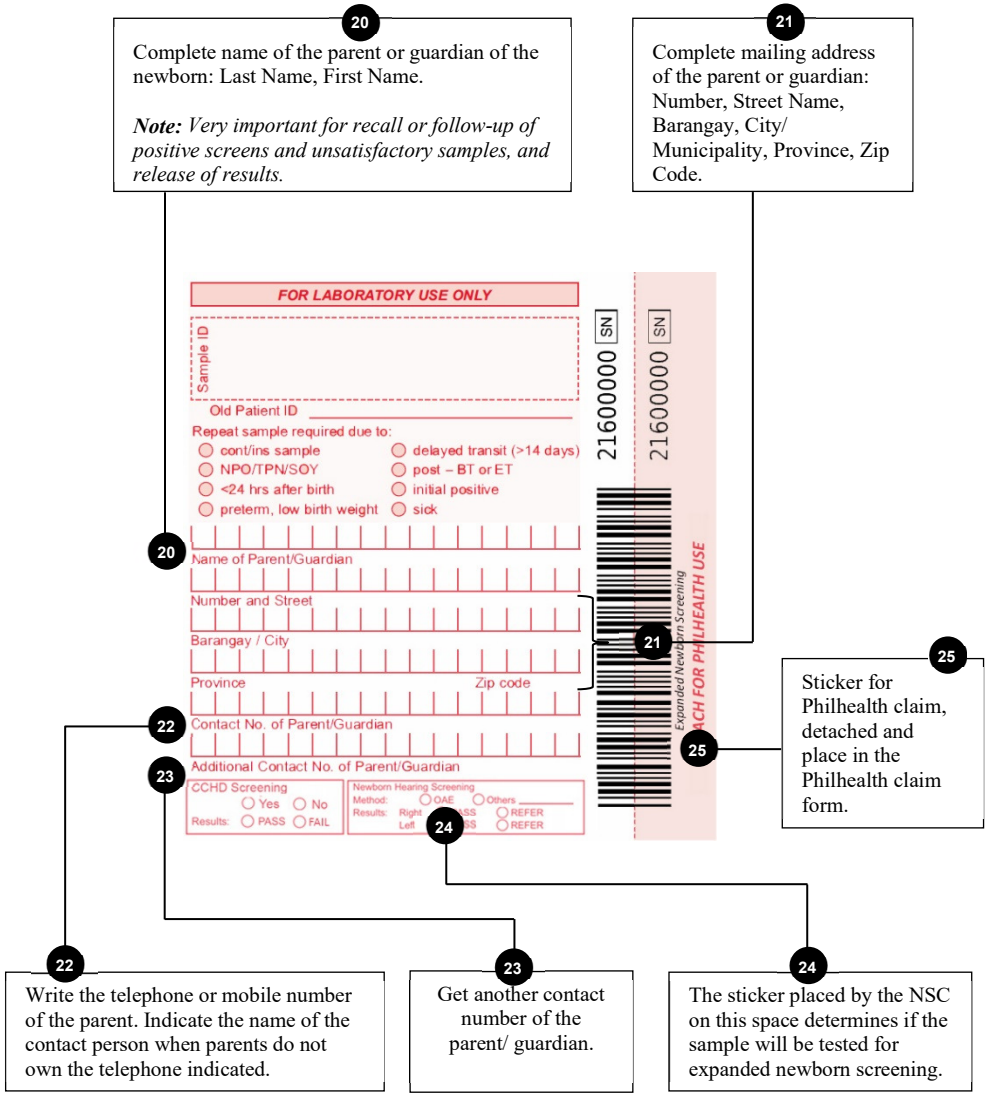


Figure 4.5 Accomplishing the newborn screening filter card: contact details.

B. Heel Prick Method

Collect the sample using heel prick method. Heel Prick is the preferred method for collecting blood samples for NBS. Practitioners must be trained to ensure that the collected samples are acceptable for proper testing and analysis.

Venous blood may be used as an alternate when blood is extracted for other tests. In this instance, remove the extracting needle before applying the blood onto the filter card. Umbilical cord sample is not an ideal sample because of high rate of false positive and false negative results.

1. Prepare the necessary materials:

   - a warm, moist towel
   - clean, powder-free gloves
   - 70% ethyl alcohol or sterile water
   - dry and wet cotton balls/swabs
   - NBS filter card (properly filled out)
   - sterile lancets (1.0mm deep by 2.5mm long)
   - micropore tape
   - drying rack

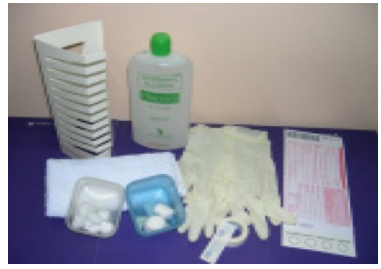


Figure 5. Supplies needed for NBS sample collection

2. Warm the baby's heel

   - To facilitate sufficient and free flow of blood, hold the baby's leg lower than the head. The temperature should not exceed 40°C.
   - Gentle rubbing of the baby's heel is another method to warm the area.

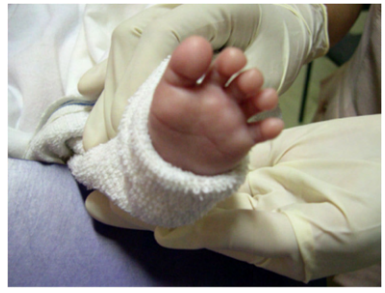


Figure 6. Warming the baby's heel.

3. Clean the puncture site

   - Clean the area thoroughly with 70% ethyl alcohol or sterile water swab.

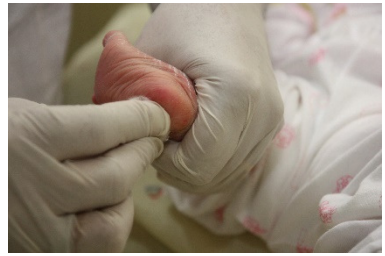


Figure 7. Cleaning the puncture site.

4. Dry the puncture site

   - Wipe the prospective puncture site with a dry cotton ball to prevent contamination of the specimen with the alcohol or sterile water.

5. Prick the heel

   - Make two punctures in quick succession on the lower lateral borders of the heel.

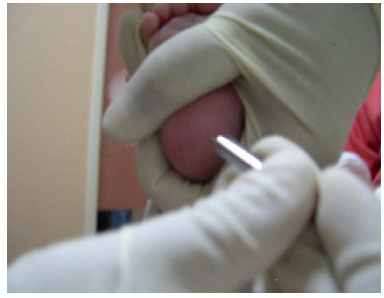


Figure 8. Pricking the baby's heel.

DO NOT PUNCTURE the following sites:

- arch of the foot
- swollen area
- previously punctured area
- fingers

  - For babies weighing less than or equal to 4.4 lbs or 2.0 kg, the puncture wound should be less than 0.85mm deep by 1.75mm long. Use the appropriate lancets.

6. Wipe the first drop of blood with dry sterile cotton to avoid contamination of the blood sample.
7. Apply gentle intermittent pressure to the area surrounding the puncture site.

   - Do not squeeze the heel too hard because this may cause interstitial fluid to leak and contaminate the specimen.
   - If blood flow slows down, release your grip and then wipe the puncture site again with DRY cotton to remove the clot.

8. Place the blood onto the filter card

   - Allow a big drop of blood to form on the baby's heel before applying it onto the filter collection card.
   - Place one drop of blood on each of the 4 circumscribed circles. Aim for complete saturation of each of the four blood spots.
   - Apply blood only on one side of the filter card. The blood should soak through the paper such that the blood spots look alike on both sides of the filter card.
   - Do not superimpose blood drops one on top of the other to prevent layering. Layering will increase the concentration of blood metabolites and may result in falsely elevated values.

Figure 9. Dropping blood on the filter card.

9. Dry the samples

   - Dry samples horizontally on a drying rack at ambient (room: 20-25°C) temperature for at least 3 hours or until completely dry. *See figure 16 on page 46.*
   - Samples must be kept in a horizontal position so that blood is distributed evenly.
   - Avoid exposure of filter collection cards to direct sunlight, artificial light, or heating instruments.

C. Acceptable specimen

Figure 10. Acceptable specimen.

D. Unacceptable Specimens

These NBS samples are unfit for testing.

Figure 11. Insufficient sample (blood collected is not adequate to perform the newborn screening test.

Figure 12. Sample diluted by plasma (with serum rings).

Figure 13. Oversaturated samples.

Figure 14. Sample appears scratched or abraded.

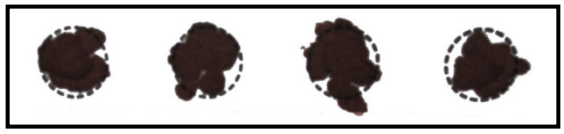


Figure 15. Clotted or layered sample.

E. Special Circumstances in Sample Collection

The following circumstances may sometimes be encountered in NBS. It is important to note and indicate these information on the NBS filter card because they are significant in the interpretation of the results.

1. Stillbirth/ Neonatal Deaths

   Label the sample: "stillbirth or neonatal death" for post-mortem sample. This should be written on the blank for Baby's Status.

2. Feeding

   - The feeding information is important for the interpretation of, GAL tests and aminoacidopathies, such as PKU and MSUD.
   - Check specific type of feeding on the filter card (Breast, Lactose Formula, Soy Formula, etc.).
   - Specify whether the patient is on intravenous fluids (IV), Total Parenteral Nutrition (TPN), Nothing Per Orem (NPO).
   - For patients on NPO or TPN, repeat collection must be done after lactose feeding is instituted or resumed for at least 24 hours. (Note: Newborns being given glucose water only are considered NPO).

3. Antibiotics

   NBS may still be done even if the newborn is on antibiotics. However, this information should be indicated on the filter card.

4. Blood Transfusion (BT)

   - Sample collection must be performed PRIOR to any blood transfusion. Details on any blood works done are important in the interpretation of results.
   - Information should be duly noted on the filter card.

5. Premature, low birth weight, or sick infants

- First sample collection of Infants who are premature (<37 weeks), low birth weight (<2000 grams), and sick[2] must be immediately done after 24 hours of life.
- A repeat NBS testing MUST be done at 28th day of life.

When requested, repeat sampling should not be delayed. Repeat sampling is required for the following:

1. Rejected samples due to unacceptability (*see Figures 9-15*)
2. Special cases:

    - Early sample collection (i.e. sample taken less than 24 hours of life)
    - Sample collected less than 48 hours after blood transfusion
    - NPO or no oral feeding since birth
    - Lack of lactose-containing feeding 24 hours prior to blood collection (i.e., those on glucose water feeding)
    - NBS sample received by the NSC more than 14 days from date of collection

A number of factors, including infant condition, treatment, and maternal status, increase the risk of missed or unreliable testing for premature, low birth weight, and sick newborns (i.e. abnormal results such as elevated amino acids may resolve at 28 days of life; thyroid function may have matured to expected levels at 28 days of life.) Initial screening cannot wait for 28 days because the goal of screening is to identify and treat every affected infant before the onset of symptoms. Delayed treatment can result in irreversible mental and physical damage. Hence, there is a need to repeat their NBS on the 28th day of life to ensure the reliability of results. There are also numerous published international and local studies to back up this protocol.

Handling and Transporting Newborn Screening Samples

Proper handling is important to prevent contamination and to maintain the integrity of the DBS. The filter collection card with DBS is extremely sensitive to environmental conditions and substances. The immediate transport of samples ensures prompt testing and analysis, allowing for the timely diagnosis of the baby's condition.

[2] Sick is any baby admitted to the neonatal intensive care unit (NICU) or requires intensive care. The intensive care being given to the baby may be because of the baby's prematurity, low birth weight, diagnosed/suspected illness, and other medical or surgical problems. A newborn admitted to the NICU for observation purposes only and is not receiving intensive care does NOT qualify as sick baby. In addition, babies receiving antibiotics for suspected sepsis or those under phototherapy for physiologic jaundice also does not qualify as sick babies. However, a baby who is not admitted to the NICU but is receiving intensive care due to prematurity, low birth weight, or diagnosed/suspected illness DOES qualify as a sick baby. The assessment as to whether the baby is receiving intensive care or not is upon the clinical judgement of the baby's attending physician.

Proper Handling of NBS Samples

DOs:

1. Air-dry NBS filter cards at room temperature (20-25ºC) for at least 3 hours on a specially designed drying rack. Blood spots should be positioned horizontally on the drying rack so that blood is distributed evenly.

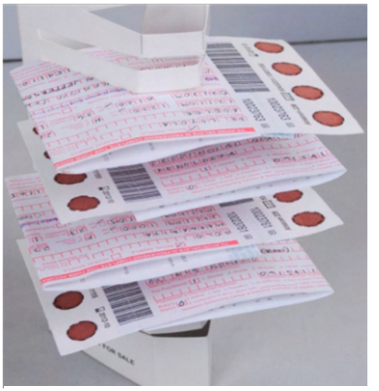


Figure 16. Proper drying of newborn screening samples.

2. Keep samples in clean, dry, open areas with dim or normal lighting.
3. Avoid exposure of filter collection cards to direct sunlight, artificial light, or heating instruments.

DON'Ts:

DON'T store filter cards in drawers, closets, or sealed plastic bags. This favors bacterial growth and may result in contamination.

Figure 17. Improper storage of filter card.

DON'T touch or smear the blood circles before, during, or after collection.

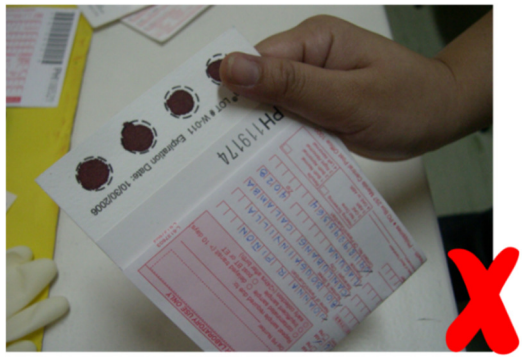


Figure 18. Improper handling of filter card.

DON'T keep cards near substances that emit fumes such as paint, varnish, aerosol sprays, insecticides and the like. Exposure to these agents will result in fixation of the blood on the filter card and prevent elution with reagents.

Figure 19. Non-exposure to chemicals

DON'T expose to intense heat or direct sunlight. Enzymes in the blood are easily destroyed by heat.

Figure 20. Non-exposure to heat.

Other sources of contamination include:

- Liquid spills as this dilutes blood concentration and results in falsely low values of metabolites
- Powdered lactose residue on hands from the gloves
- Hand lotion

Transporting NBS Samples

Preparing the samples for transport:

1. Once the sample is dry, it is ready for transport to the NSC.
2. Compare the NBS sample collected with the "Simple Spot Check" poster (available with your initial order) to make sure that the specimen is valid for testing. (*See Annex 16).*
3. Stack the dried filter collection cards alternately, so that the blood spots do not lie on top of another.
4. Wrap the stacked samples in clean paper and place inside a letter envelope. DO NOT wrap samples in plastic or put directly in plastic pouches. This encourages bacterial growth and results in contamination.
5. Accomplish the Transmittal Form completely and accurately. The transmittal form *(see Annex 17)* is an important countercheck for the samples sent by the NSF to the NSC. Ensure/countercheck that Transmittal Forms reflect the contents of every package. Write the individual names of the patients.
6. Accomplish the courier forms completely.
7. Insert the NBS samples and the accomplished transmittal form inside the courier envelope.
8. Address the envelope to NSC.
9. Arrange for regular pick up of samples with a courier. It is ideal to send NBS samples immediately after collection and air-drying. Pick-up and transport of specimens is done daily via the official courier of the NSC. Ask for the tracking number from the courier representative.

On weekends and holidays, keep the NBS samples inside the paper envelope, outside the courier bag in a cool room and send on the next working day.

Keep away the blood samples from rodents and other pests.

DO NOT BATCH NBS SPECIMENS COLLECTED ON SEPARATE DAYS. Specimens should be sent to the NSC as they come on daily basis (Monday – Friday), regardless of the number of samples.

Means of transporting DBS

NBS blood samples are sent through partner couriers. If these couriers are not available in your area, special arrangements can be made with bus companies, jeepneys, and other public means of transportation to transport NBS samples efficiently and promptly. Coordinate with the NSC for the special arrangements. To ensure that they are properly handled, packages should have special labels (i.e. do not delay, keep dry, avoid exposure to heat, etc.).

Performing the Newborn Screening Tests

Upon receipt of NBS samples at the NSC (day 1), they are sorted and assessed for suitability for testing. All samples received at the NSC are assigned a unique accession number and entered into the NBS Database.

Ideally on Day 1 to 2, the NBS tests are performed on the accepted samples. Samples are run together with internal and external controls.

NBS tests are done by qualified and trained medical technologists or laboratory scientists. Testing and analysis are done based on the ordered tests.

Expanded Newborn Screening Panel

Table 1. Disorders included in the Expanded NBS panel and the metabolites tested.

Disorder Group	Disorder		Primary Metabolite Tested
Endocrine Disorder	Congenital Hypothyroidism	CH	Thyroid Stimulating Hormone (TSH)
	Congenital Adrenal Hyperplasia	CAH	17-hydroxyprogesterone (17OHP)
Amino Acid Disorder	Homocystinuria	HCY	Methionine (Met)
	Hypermethioninemia/ Methionine Adenosine Transferase Deficiency	MAT	Methionine (Met)
	Maple Syrup Urine Disease	MSUD	Leucine (Leu)
	Phenylketonuria	PKU	Phenylalanine (Phe)
	Tyrosinemia Type I, II, III		Tyrosine (Tyr)
Fatty Acid Disorder	Carnitine Palmitoyltransferase I Deficiency	CPT1	Hexadecanoylcarnitine C0/(C16+C18) Free Carnitine (C0)
	Carnitine Palmitoyltransferase II Deficiency	CPT2	Hexadecanoylcarnitine (C16) C0/(C16+C18)
	Carnitine uptake defect	CUD	Free carnitine (C0)
	Glutaric Acidemia Type II	GA II	Butyrylcarnitine (C4) Isovalerylcarnitine
	Long Chain Hydroxyacyl-CoA Dehydrogenase Deficiency	LCHAD	Hydroxyhexadecanoylcarnitine (AC16OH)
	Medium Chain-Acyl-CoA Dehydrogenase Deficiency	MCADD	Octanoylcarnitine (C8)
	Very Long Chain-Acyl-CoA Dehydrogenase Deficiency	VLCAD	Tetradecanoylcarnitine (C14:1)
Organic Acid	3-Methylcrotonyl-CoA Carboxylase Deficiency	3MCC	Hydroxyisovalerylcarnitine (AC5-OH)
	Glutaric Acidemia Type I	GA I	Glutarylcarnitine (C5-DC)
	Isovaleric Acidemia	IVA	Isovalerylcarnitine (C5)
	Methylmalonic Acidemia	MMA	Propionylcarnitine (C3)
	Multiple Carboxylase Deficiency	MCD	Hydroxyisovalerylcarnitine (C5OH)
	Propionic Acidemia	PA	Propionylcarnitine (C3)

Disorder Group	Disorder		Primary Metabolite Tested
Urea Cycle Defect	Citrullinemia Type 1 Argininosuccinic Aciduria	CIT ASA	Citrulline (Cit)
Hemoglobinopathies	Alpha Thalassemia Beta Thalassemia Hemoglobin C Hemoglobin D Hemoglobin E Sickle Cell Disease	HgB	Hemoglobin (HGB)
Others	Biotinidase Deficiency	BTND	Biotinidase (BTD)
	Cystic Fibrosis	CF	Immunoreactive Trypsine (IRT)
	Galactosemia	GAL	Gal metabolite and GALT activity
	Glucose-6-Phosphate Dehydrogenase Deficiency	G6PD Def	G6PD enzyme activity

For more information regarding the disorders screened by the Philippine Newborn Screening Program, please refer to the Fact Sheets for Doctors and Fact Sheets for Parents at newbornscreening.ph.

Releasing Newborn Screening Results

Proper and timely relaying of results is a vital process to the NBS program, the absence of which will defeat the whole purpose of the screening program.

Whether the NBS result is positive or negative, it should be released promptly. Parents have the right to know the NBS results of their babies.

See Figure 22 on releasing of results based on baby's age.

Steps in the Relay of NBS Results

1. Relay of results from the NSC to NSF
2. Relay of results from the NSF to parents/guardian

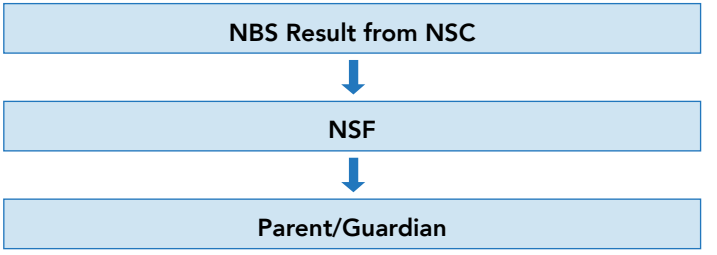


Figure 21. Flow of release of newborn screening results.

NBS Summary Report/Individual Result

The NSC generates a NBS Summary Report and Individual Result regularly (see Annex 18: NBS Summary Report and Individual Result). The Summary Report contains a listing of all babies who have undergone NBS and their respective results. The individual result is the patient's copy of the result. The NBS Summary Report and the Individual Result are transported to the NSF within 7 to 14 working days from the date the samples ware received by the NSC. The report is retained in the NSF while the Individual Result Forms are forwarded by the NSF's NBS team to the respective health practitioner of the specific newborn.

Types of NBS Results

- Abnormal NBS Results or outside normal limits
- Unsatisfactory
- Normal NBS Results or within normal limits

Normal NBS Results

The NSCs release NORMAL results (Individual Result Form and NBS summary report) to NSFs via fax or email usually on the 7th working day from the date of receipt of sample. For NSFs that do not have fax or email, hard copies of the results are sent through courier within 14 working days from the date of receipt of sample by the NSC.

The NBS Coordinator is responsible for ensuring the distribution of the individual NORMAL NBS results to the Attending Physician or Health Practitioner who attended the birth of the newborn.

When both the NBS Coordinator and the Attending Physician are not available, the result may be given directly to the parents.

The NSF must have a designated NBS area from where the NBS results can be released directly to the parents. Documentation of this direct release should be placed in the newborn's health record.

Abnormal NBS Results

The report is sent to the NBS Coordinator and the Attending Physician through fax or email *(see Annex 19: Abnormal NBS Result)* and via telephone immediately after the results are released from the laboratory. A hard copy of the abnormal NBS result is sent through courier.

The NSCs release individual NBS results for NBS samples that are positive for any one of the disorders in the NBS panel. The report contains the following information:

- Sample ID
- Patient's ID
- Mother's name
- Date of birth
- Sex
- Date of sample collection

- Hospital of collection
- Result of NBS (specific test)
- Attending Physician

The report may also contain the following:

- Actual values and normal laboratory reference ranges of the metabolites tested for each disorder
- Instructions on what to do next for elevated results

Recalling Patients

Recall is the immediate location or tracking of a newborn with a positive screen for appropriate laboratory testing to confirm the diagnosis and, when appropriate, provide treatment.

It is the act of calling the parents or guardians of the patient to inform them that the baby needs one of the following:

- Repeat blood sampling
- Confirmatory and ancillary tests

Types of Recall

- Recall of babies with positive screen
- Recall of babies with unfit/unsatisfactory sample

Recall of babies with positive screen *(see Figure 23)*

- Any baby with a positive screening result must be recalled immediately for either repeat sample collection or specific confirmatory test.
- The recall of the patient is the main responsibility of the Attending Health Practitioner. Because of his rapport with the patient's family, the health practitioner is in the best position to explain to the parents the need for further testing.

- In the absence of the Attending Health Practitioner, recall of a patient with positive screen is the responsibility of the NBS Coordinator and the NBS team of the NSF.
- NBS Coordinator may coordinate with the DOH Regional Coordinator at the DOH-CHD/MOH BARMM for assistance in recalling the patient.

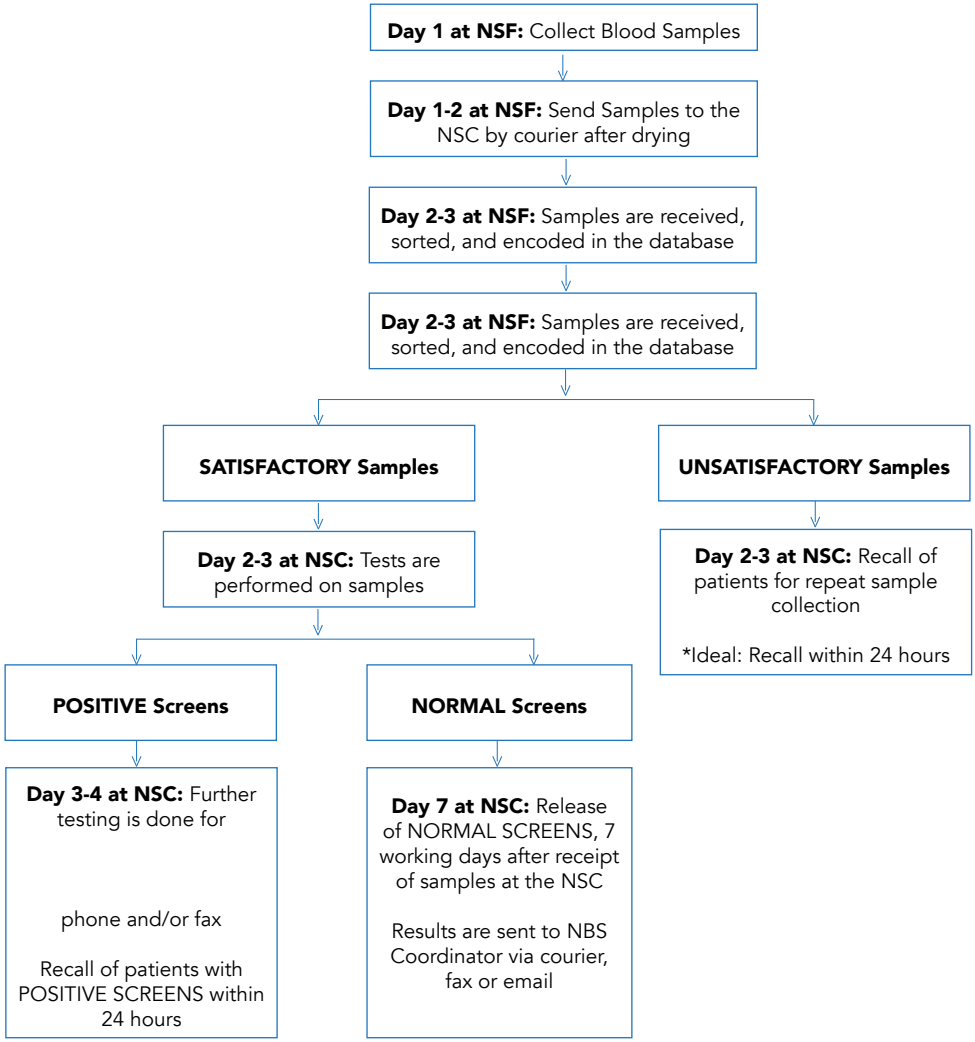


Figure 22. NBS flow from sample collection to release of results based on baby's age.

Recall of babies with NBS Samples Unfit and/or Unsatisfactory for Testing

Equally important is the recall of patients with rejected samples *(See Figure 24)*. The proper blood sample must be taken immediately in order to perform the NBS tests.

What makes a dried blood spot (DBS) not fit for testing?

- Contaminated (by liquid, dirt, abrasions, smears)
- Insufficient blood (not enough blood to perform the whole newborn screening panel)

What makes a dried blood spot (DBS) Unsatisfactory?

- Sample taken within 48 hours after blood or exchange transfusions
- Sample taken when patient is on Total Parenteral Nutrition (TPN)
- Sample taken when baby was on Nothing Per Orem (NPO)
- Early sampling (baby less than 24 hours of life)[3]
- NBS samples received at NSC more than 14 days from date of collection

    - The NSC personnel will notify the NBS Team of the NSF about the patients with unfit samples by phone, text message, or fax within 24 hours of sample receipt at the NSC.
    - When the patient is not able to return to the hospital of birth for repeat sample collection, the NBS Coordinator should direct the patient to another NSF (preferably near the patient's place of residence) for repeat sampling.

[3] Except for sick, preterm and has low birth weight baby

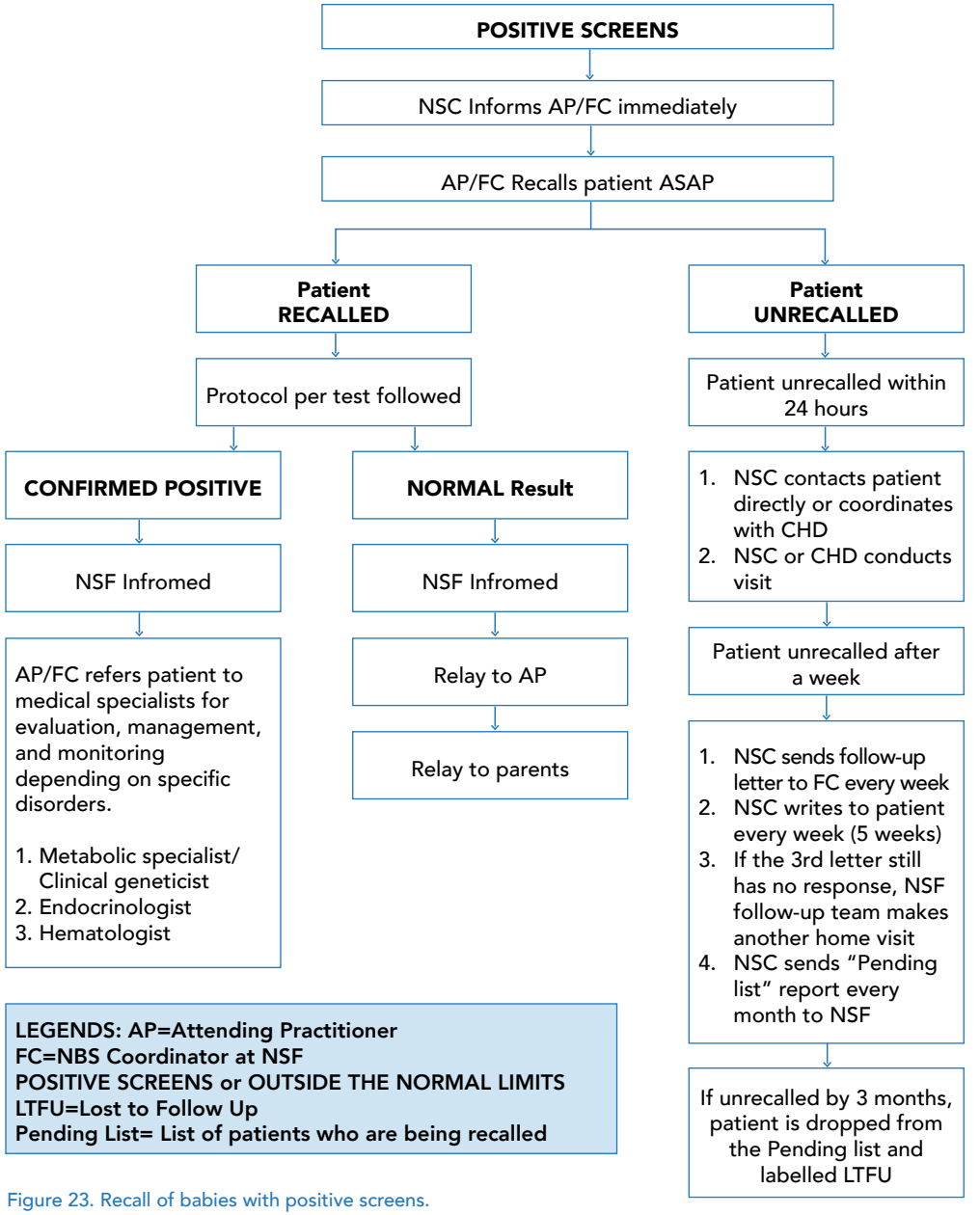
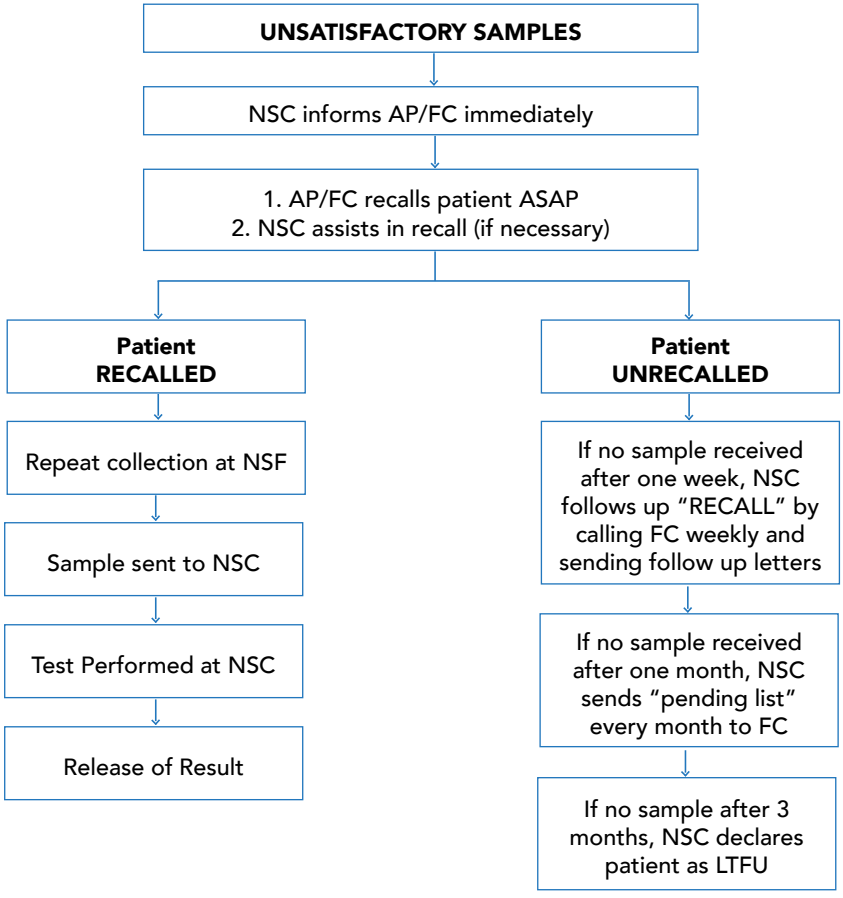


Figure 23. Recall of babies with positive screens.



LEGENDS: AP=Attending Practitioner
FC=NBS Coordinator at NSF
LTFU=Lost to Follow Up
Pending List= List of patients who are being recalled

Figure 24. Recall of babies with unsatisfactory samples.

Reasons for immediate recall of patients

Prompt recall of patients with elevated results is critical in saving babies from mental retardation or death.

A delay in the recall means a delay in the repeat collection that will delay the diagnosis and management of the disorder.

A. Means of recalling patients

- Phone calls
- Text messages
- Sending letters, telegram, fax, or email
- Utilizing tri-media advertisements in tabloid, local, and national newspapers, radio and television announcements
- Visiting patient's home
- Coordinating with the provincial health office, municipal health office, LGU and/or health center for assistance
- Coordinating with civic organizations

B. Responsibilities of the NBS Coordinator in the recall of newborns with positive screens and unsatisfactory samples

- Prompt notification of the Attending Practitioner of positive screens/unsatisfactory samples;
- Immediate notification of parents about the NBS results of their newborn if the Attending Practitioner is not around;
- Immediate facilitation of repeat blood collection from babies with elevated results or rejected samples;

    - If the baby is not around the vicinity of the NSF, facilitate repeat collection in another NSF near the patient's current residence.
    - Contact the NSRC or visit the NSRC website www.newbornscreening.ph for the list of participating NSFs.

- Ensure that all patients with unfit samples are recalled and repeat collection is done immediately.

Parents do not have to pay for repeat blood collection due to elevated NBS result.
See page 61 for the NSC card replacement procedure.

- Over-all coordination of NBS operation in the NSF; and
- Point person for communication with NSC.

C. Responsibilities of the NSC Follow-up Nurse Coordinator in the recall of newborns with positive screen and unsatisfactory samples

- Ensures that all positive screens are recalled immediately;
- Monitors all patients with positive screens until confirmation of a disorder has been made;
- In confirmed cases, ensure that patients and their records are turned over to the NBSCC for long term management;
- Documents and manages files of positive/confirmed cases;
- Acts as point person for parent queries regarding NBS disorders and results; and,
- Gives regular census of cases to the NSRC.

D. Proper Documentation

- Effective recall relies on proper documentation of information about all babies born within the catchment area of the NSF.
- Document the following information:

  - Complete address of patient
  - Contact numbers (landline and cellular or mobile phone numbers) of patient's parents or guardians
  - Contact numbers (landline and cell phone numbers) and address of individuals who can assist in the recall of the patient (i.e., neighbor, barangay captain, barangay health worker, midwife)
  - All efforts made to recall a baby and file in baby's chart

- In cases of parent refusal for further testing, secure a written refusal to document this fact *(See Annex 20: Parent Refusal Form)*
- In cases when the NSF is unable to recall a positive screen after 3 months of continuous maximal efforts, NSF must send a communication to NSC regarding this "failed recall".

Managing, Referring, and Monitoring of Patients

Prompt and appropriate management of babies with a positive screen is essential for saving these babies from the debilitating consequences of the disorders being screened.

The NCNBSS includes not only screening and diagnosis, but also short-term and long-term follow-up care through case treatment, management, and monitoring. All of the conditions identifiable through newborn screening are chronic, and therefore require medical care and other related services throughout the affected individual's lifetime. A newborn screening follow-up system in place will ensure effective disease management after diagnosis.

Short Term Follow-up

Short Term Follow – up covers recall of babies with positive screens, diagnosis of positive screens, and if confirmed positive in one of the disorders - initial treatment and management. Monitoring should be done regularly through the Attending Physician or by direct inquiry from the parents until initial treatment.

While it may be easier to contact parents directly, it is recommended that the NBS team in coordination with NSC Follow-up Head consult the Attending Practitioner and direct all communications through him/her in order to avoid miscommunication.

A. Responsibilities of NBS Coordinator

1. Referral

- Ensures that patients are referred to health facilities where confirmatory tests can be performed.
- If the appropriate confirmatory tests are not available within the area, the NBS team should facilitate the referral of the baby to the nearest health facility where confirmatory tests are available. The NBS team may call the NSC for assistance.
- Through the Attending Physician and the NSC Follow-up Head, gives advice to parents on what to do and where to go when their baby has a positive screen.

2. Management

- For NSF with medical specialists, ensures that patients are promptly evaluated and are given appropriate management.
- In the absence of a pediatric specialist in the NSF, the Attending Physician or NBS Coordinator coordinates with the NSC for acute management and for contacts of doctors with the appropriate expertise and facilitate early referral.

Long Term Management

Long-term follow-up comprises the assurance and provision of quality, continuous management, condition-specific treatment, and age-appropriate preventive care throughout the lifespan of individuals identified with a condition included in the newborn screening panel. Integral to assuring appropriate long-term follow-up are activities related to improving care delivery, including engagement of affected individuals and their families as effective partners in care management, continuous quality improvement through the continuity clinics, research into treatment options, and active surveillance and evaluation of data related to care and outcomes.

Continuity Clinic

All confirmed patients are referred to the NBSCC by the NSC for long-term management. The Continuity Clinic serves both as a NBS long term follow-up clinic and Birth Defects Continuity Clinic. A team of a part-time pediatrician, a full-time nurse, and a genetic counselor run the clinic. The principal goal of long-term follow-up is to assure the best possible

outcome for individuals with disorders identified through newborn screening and attend to patients with birth defects for long-term care and management.

A. Patient/Family-Centered Activities (Main)

- Encourage family to maintain relationship with Newborn Screening Continuity Clinic and Birth Defects Continuity Clinic to ensure continuous and effective care.
- Monitor compliance with treatment (facilitate referral to appropriate sub-specialists, therapists, nutritionists).
- Reinforce schedule of follow-up appointments and work-ups endorsed by the NSC.
- Provide follow-up counseling and anticipatory guidance to the family.
- Provide continuing education about the condition to the families and the health professionals.
- Set up patient/family support groups in coordination with NSRC.
- Coordinate with DOH-CHD/MOH BARMM in patient recall (lost to follow up cases).

B. Patient/Family-Centered Activities (Quality Assurance)

- Prepare and submit reports of the two clinics to NSRC (initial). Participate in monthly patient case audit.
- Evaluate the extent to which the birth defects or newborn screening long-term follow-up care is effective in improving the patient's health.

C. Program Activities

- Collaborate with other agency partners of the program: DOH-CHDs/MOH BARMM, NSCs, Clinical Genetics Units, CHGS, NSRC, health facilities, health practitioners, and LGUs.

D. Other Activities

- Attend to related workshops, meetings, seminars and conferences (funded by either DOH-CHDs/MOH BARMM, NSC, NSRC).

Managing Patients

NSCs transfer the roster of confirmed patients, including protocols for management and list of follow-up laboratory procedures, to the NBSCC using the prescribed Patient Endorsement Forms (please see attachments) based on the enclosed schedule.

Once patients have been endorsed under long-term follow-up care, the NBSCCs are expected to:

- Make every effort, in coordination with respective DOH-CHDs/MOH BARMM, 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.
- Facilitate referral of patients needing consults to available subspecialists in their facility or region. In cases wherein genetics evaluation and consultation is not available in their region, the continuity clinic shall utilize the Telegenetics Referral System.

Chapter 3
Managing Newborn Screening Supplies

All hospitals, birthing facilities, RHUs, health centers, and other NSFs throughout the country should have NBS specimen collection kits at all times. It is advisable that the NSF should purchase at least 1 month stock of the NBS Collection Kit. This can be estimated by getting the average monthly delivery for the past year. The NBS specimen kits are available for purchase from the NSC. The NBS Specimen Collection Kit contains the following:

- Filter paper
- Lancet
- Transmittal Form
- Brochure

Each NBS Collection Kit is good for one baby only.

Supplies

A. **Filter paper**

The filter collection card is a special grade of absorbent paper specifically designed to collect blood samples for NBS analysis. The filter paper uses a 903 Grade or equivalent with pH at 5.7 to 7.5 (test method ISO 6588-1). It has 4 circles, each measuring 1.27 centimeters in diameter and on which the drops of blood samples are collected and allowed to soak through. It has a lot number and has an expiration date.

Filter collection cards should be handled with care to avoid contamination. *See page 38* on the proper handling of NBS samples. They are best stored in a cool dry place and away from direct sunlight. Storage areas should be kept clean and free from roaches and rats.

B. **Drying Rack**

NBS specimens are individually air dried at room temperature in horizontal position by placing them on a specially designed cardboard rack. A single rack can accommodate approximately 10 filter collection cards at a time. This is included in the starter NBS collection kit. Once

drying rack becomes dilapidated after several uses, a drying rack can be requested from the NSC free-of-charge.

C. Lancets

The lancet used for NBS has rigid specifications to make it safe for the babies who may otherwise sustain deep wounds or fractures if an ordinary lancet is used. For well babies, recommended lancet size does not exceed 2.5 mm. Puncture wound depth does not exceed 2.0mm.

D. Transmittal form

The transmittal form is an important counter-check for the samples sent by the NSF to the NSC. Transmittal forms are sent back to the NSC together with the sample. Mother's name on each sample to be transmitted must be written in the transmittal form including other attached items (i.e. check payment or money order.)

E. Brochure

The pink brochure contains basic facts about newborn screening and a short description of each disorder. It is available in several dialects.

F. Simple Spot Check Poster

The Simple Spot Check poster is a visual guide showing samples of a valid specimen and invalid specimens. This is included in the NBS starter kit.

Purchasing the NBS Specimen Collection Kits

A. Ordering

- All orders for the NBS Specimen Collection Kits must be in the Purchase Order (P.O.) of the requesting NSF, duly signed by the authorized purchasing officer.
- The P.O. is then sent to the NSC through:
  - Courier or mail
  - Fax
- Minimum allowable order per P.O. is 5 sets of ENBS Specimen Collection Kits. There is no maximum limit.

B. Delivery

1. Ordered supplies are sent by the NSC through its official courier. A Sales Invoice in duplicate form accompanies the order. The original copy is retained and forwarded to the NSFs accounting department by the person who received the goods. The duplicate copy is sent back to the NSC.
2. The health personnel in charge of receiving the ordered supplies must immediately inform the NSC of any discrepancy in the delivery within the day the order was received. If no complaints are received by the NSC, then the supplies will be deemed received in good order and condition.
3. Orders will be delivered within 7 working days upon receipt of the P.O. from the NSF. The NSF will be notified of any changes in the delivery schedule.

C. Payment

1. Terms:

   - Prepaid
   - Cash on Delivery (COD)
   - 45 days (or 60 days for PHIC accredited NSFs upon request) from receipt of order and sales invoice

2. Any unpaid account after the given term will incur an interest charge of 2% per month until fully settled. NSC Unit Heads are authorized to waive this penalty and/or extend terms of payment.
3. Payment may be made through any of the following ways:

    - Cash
    - Bank to bank payment
    - Check payments
    - Postal Money Order

4. Payment Details:

    - Through online system payment, indicate the hospital code, hospital name, amount of deposit, and Sales Invoice number. Keep the deposit slip for possible reference.
    - Through regular bank payment, the original validated deposit slip should be immediately sent to the NSC for proper recording, posting and acknowledgement.

5. The invoice number for which payment is made must be indicated at the back of the deposit slip. The same must be done for check or postal money order payments.

Replacement of Filter Collection Cards

Only filter collection cards used for repeat sample collection of patients who have positive initial screening results are replaced free of charge by the NSC. The NSC must submit the list of names of patients for which a second/ repeat card was used. Replacement cards are sent in the next order.

Other administrative mechanics

Each NSC will provide detailed administrative mechanics to guide NSFs.

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Chapter 4

Training the Health Workers

For a health worker to be able to do her/his obligation of providing parents and guardians substantial information about the significance of NBS, it is imperative that they are equipped with the relevant information about NBS. Trainings at the regional level are coordinated by DOH-CHDs/MOH BARMM. Contact details of Regional Coordinators are available at www.newbornscreening.ph.

There are various levels of training for implementers of NBS. They range from simple orientation courses to formal training courses on management of congenital metabolic disorders. Below is a table of training and orientation activities on NBS. ENBS is incorporated in the training.

Facilitators Guidebook and other resources and training materials are available for download at www.newbornscreening.ph/ resources.

Health practitioners can also do self-assessment through www.newbornscreening.ph.

Table 2. NBS Training Courses

Training Course	Target Participants	Objectives	Contents	Duration	Method
Orientation courses	BHWs & other community volunteers Local Government Executives (LCE), NGOs, GOs, & other sectors	1. To provide basic information on NBS, the NBS Panel of disorders, early detection, management and follow-up 2. To elicit support for NBS	▪ NBS and its importance ▪ NBS Panel of Disorders ▪ How NBS is Done ▪ Highlights of RA 9288 ▪ Cost of NBS	1-3 hours	Lecture Testimonials Videos Flip Charts Demonstration
NBS Coordinators Training	NBS Team per NSF NBS Coordinators at CHO and PHO level	1. To provide basic orientation for health practitioners 2. To provide detailed information on NBS Operation, i.e. motivating parents, sample collection, specimen handling, logistics management, collection of fees, release of results, follow up and recall of cases	▪ NBS and its importance ▪ NBS Panel of Disorders ▪ How NBS is Done ▪ Highlights of RA 9288 ▪ Cost of NBS	½ day	Lecture Videos Testimonials Demonstrations and Return Demonstrations
NBS Clinical Training for Health Practitioners	Physicians (pediatricians, obstetricians or family physicians), nurses, midwives	1. To provide basic orientation on NBS 2. To provide information on expected roles 3. To discuss NBS referral network and NBS Continuity Clinics	▪ General Information on NBS ▪ RA 9288 and IRR ▪ NBS Operations ▪ Clinical Practice or Algorithm ▪ Expected Rates	1 day	Lecture Video Case Discussion Demonstrations and Return Demonstrations

Training Course	Target Participants	Objectives	Contents	Duration	Method
Counseling	Genetic counselors	1. To practice counseling (nutritional/genetic)	▪ General Information on NBS ▪ Principles in counseling ▪ Clinical protocols		Role play Videos Lectures Discussions

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Chapter 5

Monitoring and Evaluating Newborn Screening

Monitoring

Monitoring is the systematic and continuous process of observing and overseeing program implementation without bias. Through monitoring, one is able to keep track of activities to ensure that the program is proceeding according to plan. It enables the managers to answer questions like:

- Are the activities directed towards the program objectives?
- Are the activities being done on time as planned?
- Are good standards being maintained?
- Are the targets being achieved?

The NBS Program has several components that must be looked into:

- Education/information dissemination
- Screening process
- Release of laboratory results
- Patient recall and management
- Follow up care
- Recording & reporting - timeliness of submission, maintenance
- Quality assurance
- Financial resources

For monitoring to be useful, it should be done on a regular basis, at least once a year utilizing the Program Evaluation and Assessment (PEAS) Tool for NSF *(See Annex 21)*, which should include the following methods:

- Observation of health facility
- Review of records and reports
- Interview of health personnel

Indicators

The following indicators should provide useful data to program managers to improve program performance.

1. The percentage (%) of facilities offering NBS as compared to the total number of facilities. This reflects the accessibility of NBS services and indirectly measures the level of political support for the program.
2. The percentage (%) of babies screened as compared to the total deliveries in the NSF and the community. This reflects the efficacy of parental motivation and health worker commitment to implement the program.
3. Time in transit for specimens/reports.
4. Screening age.
5. Available kits and quality of storage.
6. The number of unsatisfactory tests or the number of babies returning for repeat collection.
7. The number of babies recalled due to a positive screening test as to the total number of cases.
8. The number of babies returning as to the number of babies who were recalled for any of the disorder or who were recalled for a repeat screen (rejected sample). This reflects the efficacy of the recall system set-up in the NSF or community.
9. The number of babies followed up and/or treated as to the total number of babies who are initially positive, confirmed positive and needing continued management per disorder.
10. The number of patients lost to follow up.
11. Educational materials available and disseminated.
12. Number of ordinances or local policies.

Evaluation

Evaluation is the process of assessing the progress of the program, its strengths and weaknesses, and seeks to offer solutions to identified problems. Evaluation is done annually.

There are several ways to do evaluation:

- Desk reviews
- Comprehensive program review
- Focused program review
- Cluster survey

- Health facility assessment

Objectives

The objective of evaluating NBS is to identify ways to strengthen and sustain NBS implementation as an essential intervention in quality newborn care.

The areas that should be evaluated include:

1. Organization and Management

   - Organization and management at all levels
   - Policies in support of NBS
   - Planning
   - Involvement of partners
   - Central level support to implementing levels
   - Budget
   - Financing mechanisms

2. Training Activities

   - Training strategies
   - Training plan and status of implementation
   - Follow-up and supervision

3. Advocacy and promotional Activities

   - Information, education and communication materials
   - Communication strategies

4. Records and reports

   - Data collection
   - Data analysis
   - Documentation process
   - National statistics regarding incidence of disorders

5. Operations/service delivery

   - Quality of service delivered
   - Coverage/accomplishments
   - Work flow
   - Systems (i.e. recall and follow up, referral)

6. Quality assurance for laboratory processes

   Periodic spot checks/ external audits of NSCs should be done regularly to immediately identify potential problems so that corrective action can be done. Any wrong information resulting from substandard laboratory processes can destroy the entire NBS Program.

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Annexes

Annex 1. Policies in the National Implementation of NBS

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
San Lazaro Compound
Rizal Avenue, Sta. Cruz
Manila, Philippines
Tel. No. 711-95-02, 711-95-03
Fax 743-18-29

0014-14

January 3, 2000

ADMINISTRATIVE ORDER
No. 1-A s. 2000

SUBJECT: Policies on the Nationwide Implementation of Newborn Screening

I. Rationale:

Newborn screening enables early detection and management of certain inborn metabolic disorders, which, if left untreated, may lead to mental retardation and even death. This procedure was introduced almost four decades ago in developed countries. In the Philippines, newborn screening was initiated by the University of the Philippines-National Institutes of Health in 1996. In a period of 3 years, statistical information were collected for some of the disorders:

Metabolic Disorder	Incidence
Congenital hypothyroidism	1:4,237
Congenital adrenal hyperplasia	1:6,844
Phenylketonuria	1:44,491
Galactosemia	1:44,491

While the incidence is low from a public health point of view, DOH is putting high priority for newborn screening in as much as the provision of quality life even for a fraction of our 2 million babies born annually deserves as much attention as survival.

II. Policy Statements:

1. The Philippine Newborn Screening Project is a collaboration between the Department of Health (DOH) and the University of the Philippines - National Institutes of Health (UP-NIH)

2. The project shall be lodged at the Family Health and Nutrition Cluster of the DOH

Signed ____ Received in the Records Section on 1/14/00

3. All DOH retained and renationalized hospitals shall participate in the project by year 2000. All other hospitals both private and government shall participate in the project by year 2004.

4. At the initial phase of the project up to year 2004, the screening process shall be primarily hospital based. It is envisioned that by year 2004, newborn screening shall be part of standard newborn care and be a national program.

5. Pilot tests involving selected health facilities shall be started prior to wide-scale community based newborn screening. It is envisioned that by year 2010, all newborn babies will be screened.

6. The scope of the project shall include 6 disorders namely: Congenital hypothyroidism, congenital adrenal hyperplasia, phenylketonuria, glucose 6 phospate dehydrogenase deficiency, homocystinuria and galactosemia. The screening fee is currently priced at P450.00. The cost is inclusive of all materials , supplies and freight which are incidental to the screening process.

7. Expenses for the screening process shall be borne by the parents, unless the hospital or the local government or NGO has a scheme providing full or partial subsidy depending on the financial capability of the parents. The Philippine Health Insurance Corporation shall hopefully implement a new package for newborn care in its insurance scheme.

8. DOH funds allocated for newborn screening shall at the initial phase of the project until year 2004 be utilized for advocacy, training of health workers and management of babies found to be positive for any of the six disorders.

9. Newborn screening shall be done through a heel prick to be performed by trained health workers. The procedure shall be done preferably on the 48th hour of life. However, in cases of early discharge, the sample collection must be done not earlier than the 24th hour from birth. In case a baby is discharged earlier than the 24th hour, the baby should be brought back to the health facility for screening within the first week of life.

10. DOH shall draft and finalize the policies pertaining to the project. It shall make the directional plan, secure funds for the project and be active in advocacy.

11. UP-NIH shall provide technical advice. At the initial phase, it will act as central laboratory taking charge of screening all specimens. UP-NIH will assist DOH in training laboratory personnel and in setting-up satellite laboratories by year 2001. In addition, it shall be responsible for monitoring laboratories for quality assurance.

12. DOH and UP-NIH shall conduct trainings for health workers to enable them to harness their skills at advocacy, organizing newborn screening teams in hospitals, RHUs, private clinics (e.g. lying-in clinics) to implement the project. Medical specialists shall be selected to undergo short course on the diagnosis and management of common metabolic disorders. Medical technologists of selected hospitals shall be trained in setting up the satellite laboratories. Physicians, nurses and health promotion officers shall be trained on genetic counselling.

13. UP-NIH is also tasked to come up with treatment protocols for each of the disorders in question and assist DOH in the preparation of IEC materials.

14. Currently the UP-NIH is the repository of all statistical information related to the project. By year 2001, the DOH registry of diseases shall be revised to include congenital metabolic disorders.

15. A newborn screening surveillance system shall be established in all regions to track down the number of infants with congenital metabolic disorders and the percentage of infants for whom appropriate management has been instituted.

16. The regional health office (RHO) shall designate newborn screening coordinators to coordinate with DOH in the implementation of the policies. The regional coordinators shall include newborn screening in the regional plan, monitor and evaluate the project. In addition , they shall advocate for newborn screening through enactment of local ordinance by LGU.

17. Newborn screening coordinators shall be designated at all levels to oversee the implementation in the province, city and catchment municipalities.

18. The RHO/PHO/CHO shall monitor the implementation of the project. They shall collate and analyze performance reports provided by UP-NIH, conduct field visits, hold conferences among implementors to discuss issues and recommend solutions.

19. The LGU may assist in the recall of patients with positive results through the PHO, CHO and district offices. They may also devise a financing scheme to assist indigent patients.

20. At the initial phase of the project up to year 2004, the hospitals, whether private or government shall be the implementing unit of the project. Each hospital shall organize a hospital coordinating team composed preferably by a pediatric consultant, an obstetrics-gynecology consultant and the chief nurse.

21. The hospital coordinating team shall perform the following tasks:

a. increase awareness among the hospital medical-nursing staff

b. devise strategies whereby parents or mothers are informed of newborn screening as early as the first prenatal visit.
c. ensure that babies are screened through a heel prick after obtaining parental consent.
d. ensure that all filter papers are promptly sent to the laboratory.
e. inform parents about the results.
f. recall patients with positive screen for confirmatory test.
g. manage and monitor patients who are confirmed to have any of the six disorders.

22. In addition to the above tasks, the hospital coordinating team shall see to it that administrative matters including correspondence, information and statistical data are collected and financial concerns are handled efficiently.

23. The NGO and other Go's shall be tapped for advocacy, financial support and assistance in recall.

24. DOH, in collaboration with UP-NIH, shall undertake a comprehensive evaluation of the project by year 2003. However, special studies may be conducted to address issues and problems that surface in the reports.

25. Research and development concerning newborn screening processes and the diseases with which it is concerned is strongly encouraged and must be included in the regional/provincial/city plans.

III. Effectivity

This Order shall take effect immediately.

ALBERTO G. ROMUALDEZ JR., M.D.
Secretary of Health

Annex 2. Presidential Proclamation

Office of the President
of the Philippines
Malacañang

Manila, January 22, 2003

DR. CARMENCITA D. PADILLA
Director
Institute of Human Genetics
National Institutes of Health
University of the Philippines
P.O. Box 297 Manila Central Post Office
Manila

Madam:

I have the honor to transmit, for information and guidance, a certified copy of Proclamation No. 540 dated January 20, 2004 entitled **"DECLARING THE 1ST WEEK OF OCTOBER OF EACH YEAR AS "NATIONAL NEWBORN SCREENING WEEK."**

Very truly yours,

MARIANITO M. DIMAANDAL
Director III, Records Office

gld.

MALACAÑANG
Manila

BY THE PRESIDENT OF THE PHILIPPINES

PROCLAMATION NO. 540

DECLARING THE 1st WEEK OF OCTOBER OF EACH YEAR AS "NATIONAL NEWBORN SCREENING WEEK"

WHEREAS, the Constitution of the Philippines provides that the "The State shall protect and promote the right to health of the people and instill health consciousness among them";

WHEREAS, pursuant to that mandate, the "Early Childhood Care and Development Act" (ECCD), was enacted, declaring it to be the policy of the state to *"promote the rights of children to survival, development and special protection with full recognition of the nature of childhood and its special needs"*;

WHEREAS, ECCD aims to establish an efficient system for early identification, prevention, referral and intervention for developmental disorders and disabilities in early childhood;

WHEREAS, newborn screening is an essential public health strategy that enables the early detection of several inheritable conditions which, if untreated, could lead to mental retardation and even death;

WHEREAS, early diagnosis and treatment of these conditions can result in the normal growth and development of the affected individual;

WHEREAS, newborn screening, which has long been an integral part of routine newborn care in many countries, is currently being administered only to two percent (2%) of Filipino newborns;

WHEREAS, there is an urgent need to conduct a national information campaign in order to create public awareness on newborn screening and generate full support for it from both public and private sectors.

NOW, THEREFORE, I, GLORIA MACAPAGAL-ARROYO, President of the Republic of the Philippines, by virtue of the powers vested in me by law, do hereby declare the First Week of October of each year as the ***"National Newborn Screening Week"*** with the Department of Health (DOH) and the

PGMA Hologram # 23898

Institute of Human Genetics of the National Institutes of Health, University of the Philippines to serve as the national focal points for purposes of commemorating this event and ensuring that information about the availability and benefits of newborn screening is expeditiously and widely disseminated to the general public.

DONE in the City of Manila, this 20TH day of Jan, in the year of Our Lord, Two Thousand and Four.

Gloria Arroyo

By the President:

ALBERTO G. ROMULO
Executive Secretary

FOIA Hologram # 23899

CERTIFIED COPY:

Annex 3. Republic Act 9288

S. No. 2707
H. No. 6625

Republic of the Philippines
Congress of the Philippines
Metro Manila

Twelfth Congress

Third Regular Session

Begun and held in Metro Manila, on Monday, the twenty-eighth day of July, two thousand three.

[REPUBLIC ACT NO. 9288]

AN ACT PROMULGATING A COMPREHENSIVE POLICY AND A NATIONAL SYSTEM FOR ENSURING NEWBORN SCREENING

Be it enacted by the Senate and House of Representatives of the Philippines in congress assembled:

ARTICLE I
GENERAL PROVISIONS

SECTION I. *Short Title* – This Act shall be known as the "Newborn Screening Act of 2004."

SEC. 2. *Declaration of Policy* – It is the policy of the State to protect and promote the right to health of the people, including the rights of children to survival and full and healthy development as normal individuals.

In pursuit of such policy, the State shall institutionalize a national newborn screening system that is comprehensive, integrative and sustainable, and will facilitate collaboration among government and non-government agencies at the national and local levels, the private sector, families and communities, professional health organizations, academic institutions, and non-governmental organizations. The National Newborn Screening System shall ensure that every baby born in the Philippines is offered the opportunity to undergo newborn screening and thus be spared from heritable conditions that can lead to mental retardation and death if undetected and untreated.

SEC. 3. *Objectives* – The objectives of the National Newborn Screening System are:

1) To ensure that every newborn has access to newborn screening for certain heritable conditions that can result in mental retardation, serious health complications or death if left undetected and untreated;

2) To establish and integrate a sustainable newborn screening system within the public health delivery system;

3) To ensure that all health practitioners are aware of the advantages of newborn screening and of their respective responsibilities in offering newborns the opportunity to undergo newborn screening; and

4) To ensure that parents recognize their responsibility in promoting their child's right to health and full development, within the context of responsible parenthood, by protecting their child from preventable causes of disability and death through newborn screening.

ARTICLE 2
DEFINITIONS OF TERMS

SEC. 4. *Definitions.* – Under this Act, the following terms shall have the meanings respectively given to them below:

1) *Comprehenstve Newborn Screening System* means a newborn screening system that includes, but is not limited to, education of relevant stakeholders; collection and biochemical screening of blood samples taken from newborns; tracking and confirmatory testing to ensure the accuracy of screening results; clinical evaluation and biochemical/medical confirmation of test results; drugs and medical/surgical management and dietary supplementation to address the heritable conditions; and evaluation

activities to assess long term outcome, patient compliance and quality assurance.

2) *Follow-up* means the monitoring of a newborn with a heritable condition for the purpose of ensuring that the newborn patient complies fully with the medicine or dietary prescriptions.

3) *Health institutions* mean hospitals, health infirmaries, health centers, lying-in centers or puericulture centers with obstetrical and pediatric services, whether public or private.

4) *Healthcare practitioner* means physicians, nurses, midwives, nursing aides and traditional birth attendants.

5) *Heritable condition* means any condition that can result in mental retardation, physical deformity or death if left undetected and untreated and which is usually inherited from the genes of either or both biological parents of the newborn.

6) *NIH* means the National Institute of Health.

7) *Newborn* means a child from the time of complete delivery to 30 days old.

8) *Newborn Screening* means the process of collecting a few drops of blood from the newborn onto an appropriate collection card and performing biochemical testing for determining if the newborn has a heritable condition.

9) *Newborn Screening Center* means a facility equipped with a newborn screening laboratory that complies with the standards established by the NIH and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.

10) *Newborn Screening Reference Center* means the central facility at the NIH 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.

11) *Parent education* means the various means of providing parents or legal guardians information about newborn screening.

12) *Recall* means a procedure for locating a newborn with a possible heritable condition for purposes of providing the newborn with appropriate laboratory testing to confirm the diagnosis and, as appropriate, provide treatment.

13) *Treatment* means the provision of prompt, appropriate and adequate medicine, medical and surgical management of dietary prescription to a newborn for purposes of treating or mitigating the adverse health consequences of the heritable condition.

ARTICLE 3
NEWBORN SCREENING

SEC. 5. *Obligation to Inform* – Any health practitioner who delivers, or assists in the delivery, of a newborn in the Philippines shall, prior to the delivery, inform the parents or legal guardian of the newborn of the availability, nature and benefits of newborn screening. Appropriate notification and education regarding this obligation shall be the responsibility of the Department of Health (DOH)

SEC. 6. *Performance of Newborn Screening*. Newborn Screening shall be performed after twenty-four (24) hours of life but not later than three (3) days from complete delivery of the newborn. A newborn that must be placed in intensive care unit in order to ensure survival may be exempted from the 3-day requirement but must be tested by seven (7) days of age. It shall be the joint responsibility of the parent(s) and the practitioner or other person delivering the newborn to ensure that newborn screening is performed. An appropriate informational brochure for parents to assist in fulfilling this responsibility shall be made available by the Department of Health and shall be distributed to all health institutions and made available to any health practitioner requesting it for appropriate distribution

SEC. 7. Refusal to be Tested. – A parent or legal guardian may refuse testing on the grounds of religious beliefs, but shall acknowledge in writing their understanding that refusal for testing places their newborn at risk for undiagnosed heritable conditions. A copy of this refusal documentation shall be made part of the newborn's medical record and refusal shall be indicated in the national newborn screening database.

SEC. 8. Continuing Education, Re-education and Training of Health Personnel. – The DOH, with the assistance of the NIH and other government agencies, professional societies and non-government

organizations, shall: (i) conduct continuing information, education, re-education and training programs for health personnel on the rationale, benefits, procedures of newborn screening; and (ii) disseminate information materials on newborn screening at least annually to all health personnel involved in material and pediatric care.

SEC. 9. Licensing and Accreditation. - The DOH and the Philippine Health Insurance Corporation (PHIC) shall require health institutions to provide newborn screening services as a condition for licensure or accreditation.

ARTICLE 4
IMPLEMENTATION

SEC. 10. Lead Agency. – The DOH shall be the lead agency in implementing this Act. For purposes of achieving the objectives of this Act, the DOH shall:

1) Establish Advisory Committee on Newborn Screening;

2) Develop implementing rules and regulations for the immediate implementation of a nationwide newborn screening program within one hundred eighty (180) days from the enactment of this Act;

3) Coordinate with the Department of the Interior and Local Government (DILG) for the implementation of the newborn screening program;

4) Coordinate with the NIH Newborn Screening Reference Center for the accreditation of Newborn Screening Centers and preparation of defined testing protocols and quality assurance programs.

SEC. 11. Advisory Committee on Newborn Screening. – To ensure sustained inter-agency collaboration, the Advisory Committee on Newborn Screening is hereby created and made integral part of the Office of the Secretary of the DOH. The committee shall review annually and recommend conditions to be included in the newborn screening panel of disorders; review and recommend the newborn screening fee to be charged by Newborn Screening Centers; review the report of the Newborn Screening Reference Center on the quality assurance of the Newborn Screening Centers and recommend corrective measures as deemed necessary.

The Committee shall be composed of eight (8) members, including the Secretary of Health who shall act as Chairperson. The other members of the Committee shall be as follows: (i) the Executive Director of the NIH, who shall act as Vice Chairperson; (ii) an Undersecretary of the DILG; (iii) the Executive Director of the Council for the Welfare of Children (iv) the Director of the Newborn Screening Reference Center; (v) three (3) representatives appointed by the Secretary of Health who shall be a pediatrician, obstetrician, endocrinologist, family physician, nurse or midwife, from either the public or private sector. The three (3) representatives shall be appointed for a term of three (3) years, subject to their being reappointed for additional tree (3) year periods for each extension.

The Committee shall meet at least twice a year. The NIH shall serve as the Secretariat of the Committee.

SEC. 12. *Establishment and Accreditation of Newborn Screening Centers*. The DOH shall ensure that Newborn Screening Centers are strategically located in order to be accessible to the relevant public and provide services that comply with the standards approved by the Committee upon the recommendation of the NIH. No Newborn Screening Center shall be allowed to operate unless it has been duly accredited by the DOH based on the standards set forth by the Committee. At a minimum, every Newborn Screening Center shall: (i) have a certified laboratory performing all tests included in the newborn screening program, ii) have a recall/follow-up programs for infants found positive of any and all of the heritable conditions; (iii) be supervised and staffed by trained personnel who have been duly qualified by the NIH; and (iv) submit to periodic announced or unannounced inspections by the Reference Center in Order to evaluate and ensure quality Newborn Screening Center performance.

SEC. 13. *Establishment of a Newborn Screening Reference Center*. The NIH shall establish a Newborn Screening Reference Center, which shall be responsible for the national testing database and case registries, training, technical assistance and continuing education for laboratory staff in all Newborn Screening Centers.

SEC. 14. *Quality Assurance* – The NIH Newborn Screening Reference Center shall responsible for drafting and ensuring good laboratory practice standards for newborn screening centers, including establishing an external laboratory proficiency testing and certification program. It shall also act as the principal repository of technical information

organizations, shall: (i) conduct continuing information, education, re-education and training programs for health personnel on the rationale, benefits, procedures of newborn screening; and (ii) disseminate information materials on newborn screening at least annually to all health personnel involved in material and pediatric care.

SEC. 9. Licensing and Accreditation. - The DOH and the Philippine Health Insurance Corporation (PHIC) shall require health institutions to provide newborn screening services as a condition for licensure or accreditation.

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SEC. 18. *Separability*. – If, for any reason or reasons, any part of provisions of this Act shall be declared or held to be unconstitutional or invalid, other provision or provisions hereof which are not affected thereby shall continue to be in full force and effect.

SEC. 19. *Effectivity*. This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulations.

Approved: APR 07 2004

JOSE DE VENECIA JR.
Speaker of the House of Representatives

FRANKLIN M. DRILON
President of the Senate

This Act which is consolidation of S. No. 2707 and H. No. 6625 was finally passed by the Senate and the House of Representative on February 2, 2004 and February 5, 2004, respectively.

ROBERTO P. NAZARENO
Secretary General
House of Representatives

OSCAR G. YABES
Secretary of the Senate

Approved: April 07, 2004

GLORIA MACAPAGAL-ARROYO
President of the Philippines

Annex 4. Implementing Rules and Regulations of RA 9288

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
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RULES AND REGULATIONS
IMPLEMENTING REPUBLIC ACT NO. 9288
OTHERWISE KNOWN AS
THE "NEWBORN SCREENING ACT OF 2004"

The following Rules and Regulations are hereby promulgated to implement the Republic Act No. 9288 otherwise known as "Newborn Screening Act of 2004", an act promulgating a comprehensive policy and a national system for ensuring newborn screening.

RULE 1 POLICY AND APPLICATION

Sec. 1. *Purpose:* These Implementing Rules and Regulations shall provide the concerned national government agencies, local government units and other public institutions, non-government organizations, people's organizations and private institutions with guidelines for the implementation of a comprehensive national policy institutionalizing the newborn screening system to ensure that every baby born in the Philippines is offered the opportunity to undergo newborn screening.

Sec. 2. *Declaration of Policy* – It is the policy of the State to protect and promote the right to health of the people, including the rights of children to survival and full and healthy development as normal individuals. In pursuit of such policy, the State shall institutionalize a National Newborn Screening System that is comprehensive, integrative and sustainable, and will facilitate at the national and local levels, collaboration among government and non-government agencies, the private sector, families and communities, professional health organizations, academic institutions, and non-governmental organizations. The National Comprehensive Newborn Screening System shall ensure that every baby born in the Philippines is offered the opportunity to undergo newborn screening and thus be spared from heritable conditions that can lead to mental retardation and death if undetected and untreated.

Sec. 3. *Objectives* – National Comprehensive Newborn Screening System shall aim to:

Page 1

a) Ensure that every newborn has access to newborn screening for certain heritable conditions that can result in mental retardation, serious health complications or death if left undetected and untreated;

b) Establish and integrate a sustainable newborn screening system within the public health delivery system;

c) Ensure that all health practitioners are aware of the advantages of newborn screening and of their respective responsibilities in offering newborns the opportunity to undergo newborn screening; and

d) Ensure that parents recognize their responsibility in promoting their child's right to health and full development, within the context of responsible parenthood, by protecting their child from preventable causes of disability and death through newborn screening.

Sec. 4. *Definition of Terms* – For the purposes of this Act:

a) **Accreditation** - a formal authorization issued by the DOH to an individual, partnership, corporation or association and to the Newborn Screening Center. It must comply with the mandatory requirements as enumerated in the attached annexes and with the input, process and outcome standards as prescribed in the Manual of Operations for Newborn Screening Center.

b) **DILG –** refers to the Department of the Interior and Local Government

c) **DOH -** refers to the Department of Health, the lead agency in implementing this Act

d) **Follow-up** - refers to the monitoring of a newborn with a heritable condition for the purpose of ensuring that the newborn patient receives the appropriate medicine or dietary prescriptions.

e) **Health institutions -** refer to hospitals, health infirmaries, health centers, lying-in centers or puericulture centers with obstetrical and pediatric services, whether public or private.

f) **Healthcare practitioner** - refers to physicians, nurses, midwives, nursing aides and traditional birth attendants.

g) **Health professional societies** - refer to the national organizations of recognized health societies in the country.

h) **Heritable condition** - any condition that can result in mental retardation, physical deformity or death if left undetected and untreated and which is usually inherited from the genes of either or both biological parents of the newborn.

i) **IRR**- refers to the Implementing Rules and Regulations.

j) **LGU** - refers to the Local Government Unit.

k) **National Comprehensive Newborn Screening System-Treatment Network –** refers to the tertiary hospitals equipped to diagnose and manage the confirmed cases.

l) **NIHP -** refers to the National Institutes of Health, Philippines.

m) **Newborn** - a child from the time of complete delivery to thirty (30)days old.

n) **Newborn screening** (NBS) - the process of collecting a few drops of blood from the newborn onto an appropriate collection card and performing biochemical testing for determining if the newborn has a heritable condition.

o) **Newborn Screening Center (NSC)**- a facility equipped with a newborn screening laboratory that complies with the standards established by the NIHP, and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.

p) **Newborn Screening Reference Center (NSRC)-** central facility at the NIHP 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 NBS program, oversees content of educational materials, recommends establishment of NSCs and acts as the Secretariat of the Advisory Committee on Newborn Screening.

q) **Newborn Screening Specimen Collection Kit –** materials needed in collecting NBS samples namely, filter collection card, lancet, information materials, , etc, which can be procured at the NSC.

r) **Parent Education** - the various means of providing parents or legal guardians information about NBS.

s) **Participating Health Institutions** – health institutions offering newborn screening services such as, but not limited to, motivation of parents, collection of blood sample and recall.

t) **PHIC -** refers to the Philippine Health Insurance Corporation.

u) **Recall** –a procedure for locating a newborn with a positive screening results from a possible heritable condition for purposes of providing that newborn with appropriate laboratory testing to confirm the diagnosis and, as appropriate, to provide treatment.

v) **Treatment** –provision of prompt, appropriate and adequate medicine, medical and surgical management or dietary prescription to a newborn for purposes of treating or mitigating the adverse health consequences of a heritable condition.

w) **UP** - refers to the University of the Philippines.

RULE II NATIONAL COMPREHENSIVE NEWBORN SCREENING SYSTEM.

Sec. 5. *National Comprehensive Newborn Screening System (NCNBSS*) shall *refer* to a NBS system that includes, but is not limited to:

a) Education of relevant stakeholders;

b) Collection, transport, biochemical screening, and reporting on result of blood samples taken from newborns;

c) Tracking and confirmatory testing to ensure the accuracy of screening results;

d) Clinical evaluation and biochemical/medical confirmation of follow-up test results;

e) Administration of drugs and/or medical surgical management and/or dietary supplementation to counter adverse effects of the heritable conditions; and

f) Monitoring and evaluation of the NCNBSS.

Sec. 6. *Obligation to Inform.* 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 LGU 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.

Sec 7. *Performance of* NBS. –NBS shall be performed after twenty-four (24) hours of life but not later than three (3) days from complete delivery of the newborn. A newborn placed in intensive care in order to ensure survival may be exempted from the three (3)-day requirement but should be tested by seven (7) days of age.

a) Compliance to NBS shall be the joint responsibility of the parent(s)/legal guardians and health practitioner or other person delivering the newborn to ensure that NBS is performed;

b) Health practitioners shall fully inform their patients' parents, or legal guardians about the availability, nature, and benefits of NBS;

c) Collection of samples may be performed by any trained health worker such as physicians, medical technologists, nurses and midwives;

d) NBS specimens shall be properly transported to the accredited NSCs by courier or any other fast and timely mode of transport within twenty four (24) hours following collection of the sample;

e) NBS laboratory testing shall be performed by DOH-accredited NSCs.

Any laboratory results indicating an increased risk of a heritable disorder (i.e. positive testing result) shall be immediately released, within twenty-

four (24) hours, so that confirmatory testing can be performed as provided in Section 8.

Negative screens shall be released seven (7) working days after receipt at the NSC. .

Sec. 8. *Recall.* A newborn with a positive result shall be located and recalled for confirmatory testing as soon as possible.

a) A newborn identified at high risk (positive screening result) for a heritable disorder shall be recalled immediately to confirm the diagnosis. The Municipal Health Office, City Health Office, Provincial Health Office and District Health Office shall be involved in the recall process;

b) The NSC shall notify the participating health institution about the immediate recall of the newborn with a positive screening result. Every collecting health facility shall designate a person or office responsible in the recall of the newborn;

c) The NSC shall likewise inform the designated person of the CHD or its equivalent to assist in the immediate recall of newborn with positive screen;

d) The attending health practitioner shall assist the participating health institution in locating and recalling the patient;

e) Once located, the newborn with confirmed diagnosis shall be referred for treatment and management to a duly licensed physician or a medical specialist such as but not limited to, neonatologist, pediatric endocrinologist and geneticist. Prompt management of newborns with positive screen is essential to prevent the debilitating consequences or death of the newborn;

f) Once contacted, the parents with assistance of the respective LGU shall have the primary responsibility to ensure that their newborn receive appropriate confirmatory testing as soon as possible.

Sec. 9. *Referral and Management of Positive Cases.*

a) The total management of patient with confirmed diagnosis shall be referred to the NCNBSS Treatment Network;

b) All NCNBSS Treatment Network shall follow the DOH- approved clinical protocol in the management of patients diagnosed in any of the disorders included in the newborn screening panel.

Sec. 10. *Monitoring of patients.* Monitoring and follow up of patients confirmed to have the disorders shall be done regularly by the attending physician, appropriate subspecialist or Rural Health Unit (RHU).

Report forms about the status of the patients shall be accomplished by the attending physicians to be submitted to the NSCs.

Sec. 11. *Refusal to be Tested.* A parent or legal guardian may refuse testing on the grounds of religious beliefs, but shall acknowledge in writing their understanding that refusal for testing places their newborn at risk for mental retardation or death of undiagnosed heritable conditions. A copy of this refusal documentation shall be made part of the newborn's medical record and refusal shall be indicated in the national NBS database.

Sec. 12. *Continuing Education, Re-education and Training of Health Personnel.* To ensure awareness of all health personnel, the DOH, LGUs, and the academe with the assistance of the NIHP and other government agencies, professional societies and non-government organization shall:

a) Conduct continuing information, education, re-education and training programs for health personnel on the rationale, benefits, procedures of NBS;

b) Disseminate information materials on NBS at least annually to all health personnel involved in maternal and pediatric care;

c) Integrate information in existing education programs for medical and paramedical professionals.

RULE III IMPLEMENTATION

Sec. 13. *Lead Agency.* The DOH shall be the lead agency for implementing the NCNBSS. DOH shall have the following responsibilities:

a) Fully utilize the efforts and resources of various offices within the DOH, NIHP, PHIC, and health facilities, concerned health personnel and workers to implement the NCNBSS;

b) Establish the Advisory Committee on Newborn Screening (ACNBS);

c) Coordinate with the Department of the Interior and Local Government for implementation of the NCNBSS;

d) Coordinate with the NSRC for the accreditation of NSC and preparation of defined testing protocols and quality assurance programs;

e) Coordinate with all health professional societies in an advocacy campaign on behalf of the comprehensive NBS system;

f) Integrate NBS in the current health care delivery system. NBS shall be an integral part of all public health programs. It should be a routine procedure for newborns in public and private health, hospital and birthing facilities;

g) Ensure that a network for the prompt recall of positive cases is established in collaboration with LGUs, government agencies and other Non Government Organizations;

h) Ensure that a network of facilities for referral and management of all positive cases is established;

i) Formulate protocols in the referral and management of the positive cases in collaboration with the Philippine Society for Pediatric Metabolism and Endocrinology and the IHG – NIHP;

j) Develop referral centers and identify referral teams in strategic areas for referral and management of patients with any of the disorders;

k) Ensure inter-agency collaboration through inclusion of NBS in the agenda of existing committees on children's health and welfare. In such venues, the following agencies shall be represented: DOH, NIHP, DILG and other relevant health professional organizations;

l) Ensure quality and sustainability of NBS system through the establishment of NSRC as well as its attendant requisites.

Sec 14. *Major Stakeholders.* To ensure implementation of NCNBSS, the agencies/organization identified below shall have the following responsibilities:

A. *Health Facilities, i.e. Hospitals, birthing facilities, rural health units and health centers*

a) Integrate NBS in its delivery of health services;

b) Serve as collecting health facility for NBS;

c) Coordinate with a duly accredited NSC;

d) Ensure that adequate and sustained NBS services such as information, education, communication, screening, recall and management of identified cases are being provided in the hospital;

e) 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;

f) Establish an appropriate financial system that will ensure effective and efficient collection of fees and payment of NBS services to the NSC;

g) Conduct orientation and/or training of hospital staff on NBS;

h) Monitor and evaluate the implementation of NBS within in the institution;

i) Define creative financial packages to make NBS accessible particularly among the economically deprived populace.

B. *Department of the Interior and Local Government shall:*

a) Encourage LGUs to implement RA 9288, "The Newborn Screening Act of 2004" and extend total cooperation in the implementation of the said law;

b) Assist the DOH in the monitoring and evaluation of the program implementation.

C. *Local Government Units shall:*

a) Develop capabilities of health workers;

b) Issue local ordinances and resolutions that integrate NBS in the delivery of health delivery system;

c) 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);

d) Establish a functional case management referral system with strategically accessibleNCNSS treatment network;

e) Establish coordination and networking among concerned agencies in NBS implementation;

f) Monitor and evaluate the newborn screening implementation in their localities;

h) Explore/encourage creative financial packages to make NBS accessible particularly among the economically deprived populace;

i) Perform other roles and responsibilities as deemed necessary for the implementation of this Act.

D. *Academe, Health Professional Societies, National Organizations of Health Professionals shall:*

a) Ensure that all its members are aware of the significance of NBS to their clients, their families and the society at large;

b). Define mechanism that will ensure and monitor that its members are doing their obligations to inform parents about the significance of NBS;

c). Recommend the inclusion of NBS as part of the curricula of all allied health professions;

E. *Council for the Welfare of Children shall:*

a) Integrate NBS in the establishment of the system for early identification, prevention, referral and intervention of developmental disorders and disabilities in early childhood;

b) Promote NBS as an integral part of the Early Childhood and Care Development (ECCD) programs implemented at the national and local levels;

c) Provide avenues in developing innovative advocacy and communication approaches in partnership with civil societies, NGOs and other groups;

d) Include NBS-related indicators in the Subaybay Bata and Macro-Monitoring system for children.

RULE IV ADVISORY COMMITTEE ON NEWBORN SCREENING

Sec. 15. *Advisory Committee on Newborn Screening (ACNBS).* To ensure sustained inter-agency collaboration, the ACNBS shall be created and made an integral part of the Office of the Secretary of the DOH.

Sec. 16. *Functions.* The ACNBS shall have the following functions:

a) Review annually and recommend conditions to be included in the NBS panel of disorders;

b) Review and recommend the standard NBS fee to be charged by NSCs;

c) Review the report of the NSRC on the quality assurance of the NSCs; and

d) Recommend corrective measures as deemed necessary.

Sec. 17. *Composition of the Committee.* The Committee shall be composed of eight (8) members:

a) Secretary of Health, who shall act as Chairperson;

b) Executive Director of the NIHP, who shall act as Vice Chairperson;

c) Undersecretary of the DILG;

d) Executive Director of the Council for the Welfare of Children;

e) Director of the NSRC; and

f) Three (3) representatives appointed by the Secretary of Health who shall either be a pediatrician, obstetrician, endocrinologist, family physician, nurse or midwife, from either the public or private sector. The three (3) representatives shall be appointed for a term of three (3) years, subject to their being reappointed for additional three (3) year periods for each extension.

Sec. 18. *Meetings.* The ACNBS shall meet at least twice a year. The NIHP shall serve as the Secretariat of the Committee.

RULE V NEWBORN SCREENING FEES

Sec. 19. *Newborn Screening Fees.*

a) Expenses for the NBS tests shall be the responsibility of the parents/guardian of the newborn;

b) The government and private health facilities are highly encouraged to develop a scheme providing partial or full subsidy depending on the financial capability of the parents;

c) A standard NBS fee covering all program costs shall be implemented by all NSCs, as approved by the ACNBS. A payment schedule shall also be imposed on all participating health institutions so that the NSC may stay financially solvent;

d) A health facility may collect a reasonable fee for the collection of samples, which shall not be greater than the maximum allowable service fee prescribed by DOH.

e) NSRC shall collect the percentage of the NBS fees earmarked for the DOH - Centers for Health Development (CHD) or its future equivalent from all hospitals, birthing facilities and other collecting units;

f) NSRC shall transfer earmarked funds to all DOH CHDs or its future equivalent..

Sec. 20 . PHIC *Benefit Package and Other Health Insurance-Related Concerns.*

a) The PHIC shall include cost of NBS in its benefit package of its members;

b) PHIC shall only reimburse NBS tests done in DOH accredited NSCs;

c) A newborn shall be considered a dependent of a PHIC member;

d) Newborn Screening for disorders included in the NBS panel approved by ACNBS shall be considered nationally accepted screening tests for inborn errors of metabolism and shall be considered as "medically necessary";

e) For other health facilities, i.e. lying in and birthing facilities, PHIC shall develop a reimbursement scheme to cover the newborns similar to the benefits of newborns born in the hospital facilities;

f) Private insurance companies, Health Management Organizations and community-based health care organizations shall include payment for NBS as a standard benefit to their members.

Sec 21. *NBS Specimen Collection Kits*

a) All hospitals, birthing facilities, Rural Health Units, Health Centers and other collecting units throughout the country shall have NBS Specimen Collection Kits at all times;

b) The cost of the NBS Specimen Collection Kits shall be based on the amount prescribed by the ACNBS;

c) Members of the PHIC may apply for reimbursement of the cost of NBS Specimen Collection kits;

d) For indigent members, PHIC shall devise a scheme that shall not entail a cash advance for NBS.

SEC 22. *Usage of NBS Fees.* Guidelines on the usage of funds, as approved by the ACNBS, shall be formulated by the NIHP and DOH. The NBS fee shall be applied to, among others, testing costs, education, sample transport, follow-up and reasonable overhead expenses. To ensure sustainability of the NCNBSS, the NBS fee shall be divided and set aside for the following purpose:

a) At least four percent (4%) to the DOH - CHDs or its future equivalent for:

   i. Follow-up service of patients with positive screening result by personnel hired for the NBS unit based at CHD;
   ii. Education and other activities directly related to the provision of NBS services;
   iii. Incentives for RHU collecting health units at least 2 % of the money allocated to the CHD;
   iv. Staff development of the personnel of the NBS unit based at the CHD, i.e. attendance of training seminars and official meetings of the DOH and the NIHP,
   v. Capital outlay, i.e. vehicle
   vi. Maintenance and operating expenses of the program
   vii. Cost of repeat samples due to insufficient and unsatisfactory samples of patients in their catchment area

b) At least four percent (4%) to the NSC for human resource development and equipment maintenance and upgrading;

c) At least four percent (4%) to the NIHP-NSRC for overall supervision, training and continuing education, maintenance of national database, quality assurance program and monitoring of the national program; and

d) The balance for the operational and other expenses of the NSC.

RULE VI NEWBORN SCREENING CENTERS

Sec. 23. *Establishment of Newborn Screening Centers (NSC).*

a) No NSC shall be allowed to operate unless it has been duly accredited by the DOH based on the standards and procedural guidelines approved by the Committee as enumerated in the attached annexes, which is an integral part of this IRR and the Manual of Operations for NSC formulated by the NSRC;

b) The establishment and accreditation of either free-standing or hospital-based NSC shall be phased. It shall take into consideration: strategic and geographical access to the public, data on the number of live births in each of the following areas in relation to the minimum required number of tests run (at least 50,000 samples per annum), the network component including the availability of courier services and the other NCNBSS policies.

Initially, there shall be four (4) NSCs to serve the whole country. However additional NSCs shall be established upon the recommendation of the NSRC;

d) NSCs shall make available their records to the team, including their financial books to determine compliance with fee structures and other accreditation rules and regulations.

Sec. 24. *Licensing and Accreditation.*

a) The DOH through the Bureau of Health Facilities and Services (BHFS) shall include, among others, the provision of NBS services in the licensing requirements for hospitals and birthing facilities;

b) PHIC shall include, among others, proof of NBS services in the accreditation of health facilities for quality pediatric services;

c) The NSC shall issue proof of NBS services.

RULE VII ESTABLISHMENT OF NEWBORN SCREENING REFERENCE CENTER

Sec. 25. *Establishment of a Newborn Screening Reference Center* (NSRC). The NIHP shall establish a NSRC. It has the following functions:

a) Be responsible for the national testing database and case registries, training, technical assistance and continuing education for laboratory staff in all NSCs;

b) Define the testing and follow-up protocols for NSCs;

c) Maintain an external laboratory proficiency-testing program;

d) Oversee the national testing database and case registries;

e) Report to the DOH the NSCs found violating these rules and regulations and those performing and providing NBS procedures and services without any DOH accreditation;

f) Participate in consultation and evaluation activities initiated by BHFS in relation to the NSRC and the NSCs performance and in improving implementation of these rules and regulations.

Sec. 26. *Quality Assurance*. All NSC's shall strictly follow the prescribed guidelines of good laboratory practices. The NSRC shall be responsible for drafting and ensuring good laboratory practice standards for NSCs, including establishing an external laboratory proficiency testing and certification program. It shall also act as the principal repository of technical information relating to NBS standards and practices, and shall provide technical assistance to NSCs needing such assistance.

Sec. 27. *Database*.

a) All NSCs shall coordinate with the NSRC for consolidation of patient databases;

b) The NSRC shall maintain a national database of patients tested and a registry for each condition;

c) The NSRC shall submit reports semi-annually or more frequently as the need arises to the ACNBS and to the DOH on the status of and relevant health information derived from the database.

NSRC shall prepare a plan for long-term outcome evaluation of NBS utilizing the cases registries. The plan shall be developed within one (1) year of passage of this Act in consultation with the ACNBS. Implementation of this plan shall become a responsibility of the ACNBS.

RULE VIII FINAL PROVISIONS

Sec. 28. *Repealing Clause* – All general and special laws, decrees, executive orders, proclamations and administrative regulations, or any parts thereof, which are inconsistent with this Act are hereby repealed or modified accordingly.

Sec. 29-. *Separability* – If, for any reason, any part of provisions of this Act shall be declared or held to be unconstitutional or invalid, other provision or provisions hereof which are not affected thereby shall continue to be in full force and effect.

Sec 30. *Effectivity* – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

MANUEL M. DAYRIT, MD, MSc.
Secretary of Health

ANNEX 1

MANDATORY ACCREDITATION REQUIREMENTS FOR NSCs

1. SERVICE CAPABILITY

1.1 Testing Capability:

1.1.1 Analyzing a minimum of one hundred and fifty (150) samples a day utilizing testing methods approved by the NSRC

1.1.2 Testing for the following disorders included in the NBS package currently approved by the ACNBS for NBS:

1.1.2.1 Congenital Adrenal Hyperplasia (CAH)
1.1.2.2 Congenital Hypothyroidism (CH)
1.1.2.3 Phenylketonuria (PKU)
1.1.2.4 Galactosemia (GAL)
1.1.2.5 Glucose 6 Phosphate Dehydrogenase Deficiency (G6PD)

1.1.3 Interpreting and reporting test results for each disorder based on pre-determined analytical ranges and expected norms.

1.2 Administrative and Network Capability:

1.2.1 Providing the necessary NBS Specimen Collection Kits (filter collection card, lancets, information materials, etc) to all health facilities within its coverage.

1.2.2 Releasing results of all analytical testing for all samples received from health facilities within its coverage.

1.2.3 Informing NBS coordinators of health facilities of patients whose results are positive or unsatisfactory at the time of initial screening.

1.2.4 Monitoring and referring patients with abnormal results to NCNSS treatment network.

1.2.5 Coordinating with government and non-government agencies for the establishment of a network for NBS recall and follow-up.

1.2.6 Establishing and maintaining databases of patients screened, analytical results, and follow-up outcome.

1.2.7 Providing required information from databases to NSRC via computerized linkages

1.2.8 Transporting samples from the health facilities to the NSC

1.2.9 Receiving specimens on a daily basis five (5) working days per week from courier or other appropriate delivery services

1.2.10 Storing specimens in a manner deemed appropriate

1.2.11 Maintaining detailed documentation logs of testing and follow-up.

2. PERSONNEL

2.1 A licensed physician with at least one (1) year training/ orientation and experience in running a NBS program or three (3) years of equivalent experience in a closely allied situation as approved by the NSRC.

2.2 A licensed biochemist, chemist, medical technologist or microbiologist with at least one (1) year of satisfactory training/ orientation in NBS Laboratory Management or three (3) years of experience in related field.

2.3 Three appropriately licensed scientists (biochemist, chemist, medical technologist or microbiologist) with at least three (3) months of laboratory testing experience in performing the tests specified or one (1) year of equivalent testing experience in a clinical laboratory.

2.4 A licensed nurse with at least three (3) months of experience working/training in NBS or six (6) months of equivalent experience in a public health case management program.

3. EQUIPMENT/ INSTRUMENT/ REAGENTS

3.1 Database system compatible with that of the NSRC

3.2 Equipment appropriate for performing analytical testing on dried blood spots (3 mm diameter - ~1.5 µL serum) for Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Phenylketonuria, Galactosemia and Glucose-6-Phosphate Dehydrogenase deficiency

3.3 Fume hood necessary for any of the analytical procedures specified

3.4 Automated puncher capable of cleanly punching 3 mm paper punches

3.5 Manual paper punch capable of cleanly punching 3 mm paper punches

3.6 Multiple pipettor capable of delivering appropriate reagent volumes for any of the procedures specified (i.e. generally considered to be volumes of 10 ㎖, 50 ㎖ or 100 ㎖)

3.7 Eppendorf pipettes, if deemed appropriate, calibrated to deliver volumes of 100 ㎖ and 200 ㎖

3.8 Filter paper collection cards (S&S 903) compatible with those designed for use by the NSRC
3.9 Lancets with tip approximately 2.0 mm long sufficient for heel-prick
3.10 Disposal system for hazardous and non-hazardous materials
3.11 Drying rack for horizontal drying of filter paper collection cards
3.12 Storage area of used filter paper cards (a small room with temperature and humidity control is preferred)
3.13 Freezer with temperatures maintained between –20 to –10 C
3.14 Refrigerator capable of maintaining constant temperatures between 4-8 C.

4. FACILITY

4.1 Minimum of one hundred (100) square meters working floor area
4.2 Area for blood collection and storage
4.3 Five (5) work-benches to run the five (5) tests Each work bench approximately three (3) ft. long and five (5) ft. wide.
4.4 Sink for waste disposal
4.5 Source of de-ionized water
4.6 Waste disposal facilities for any hazardous materials generated

ANNEX 2

GUIDELINES IN THE APPLICATION FOR ACCREDITATION

A Certificate of Accreditation shall be granted in accordance with the prescribed accreditation requirements and on the basis of specific conditions and limitations. The accreditation as herein granted as well as any right under the accreditation cannot be assigned or otherwise transferred directly or indirectly to any party. A separate accreditation shall be required for all NSC or branches maintained in separate premises. Violation of this IRR, its Manual of Operations for NSC and other related issuances shall be a ground for suspension or revocation of the accreditation.

1. **PROCEDURES FOR APPLICATION OF ACCREDITATION:**

1.1 Applicant requests for relevant information and prescribed forms from the BHFS on the proposed NSC, in person, or through mail, e-mail, fax transmittal or the internet.

1.2 Applicant accomplishes required documents and submits them in person or through mail to the BHFS

Documentary Requirements:

Initial Accreditation:

a. BHFS-NSC Form No. 1-01: Application for DOHAccreditation as a NSC
b. List of personnel involved in NBS, indicating names, positions, job description, PRC license number and relevant training
c. List of equipment/instrument/ reagents for NBS if available

Letter of Intent signifying willingness to:

- comply with the prescribed Technical and Administrative Manual of Operations for NBS, and
- participate in Quality Assurance Program

Renewal of Accreditation:

BHFS-NSC Form No. 2-01: Application for Renewal of DOH Accreditation as a NSC

a. List of Personnel involved with NBS, indicating names, positions, job description, PRC license number and relevant training
b. List of equipment/instrument/ reagents for NBS

c. List of NBS procedures performed, services offered and statistical accomplishment report for the past three (3) years
d. Copy of the NSCs Technical and Administrative Manual of Procedures for NBS.
e. Documentation of Quality Assurance Program implementation

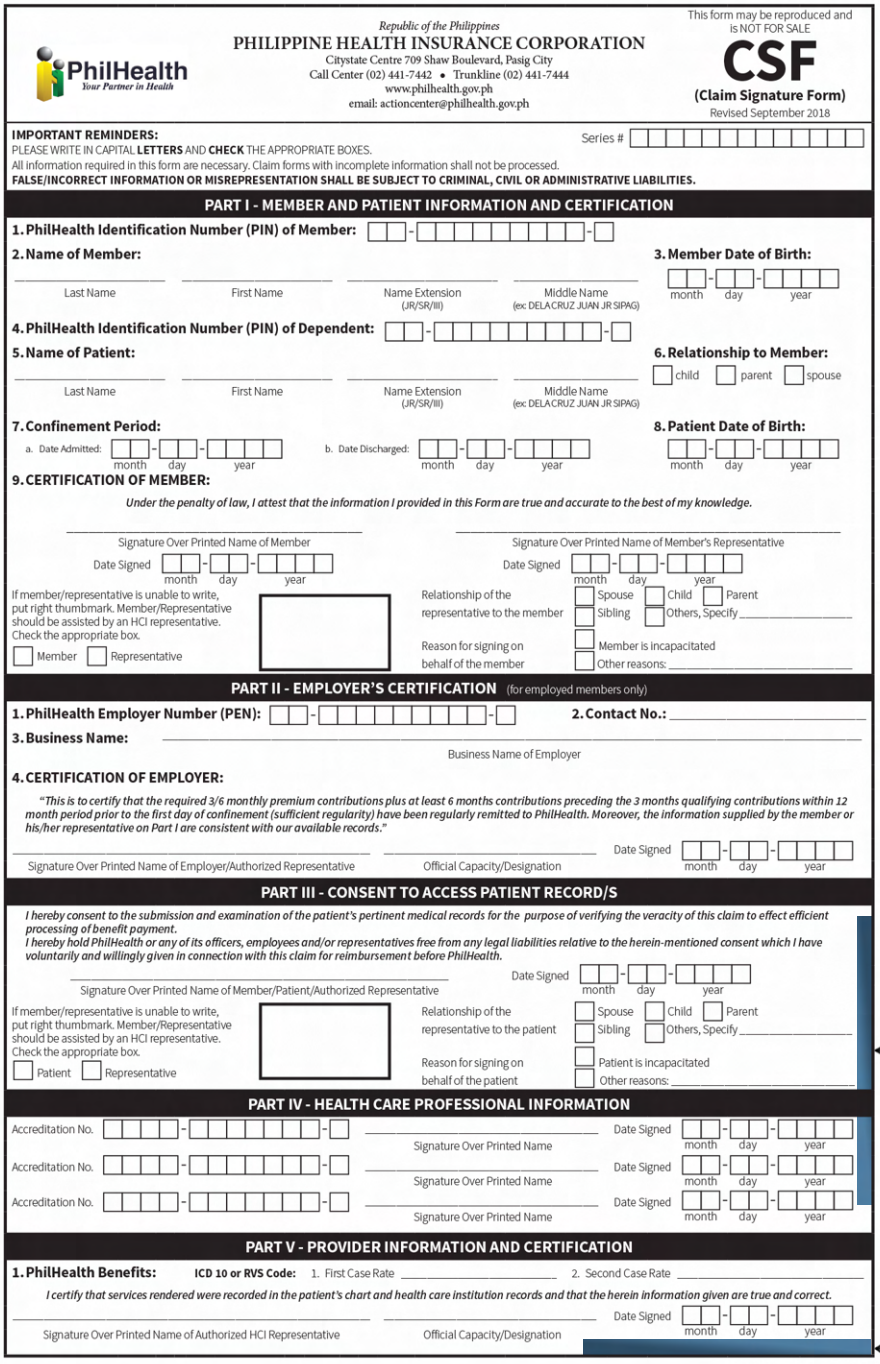
1.3 BHFS together with NSRC evaluates application based on the selection criteria that includes the pre-identified regional areas for NSCs to serve and compliance with documentary requirements
1.4 BHFS informs the applicant of the result of evaluation. If favorable, applicant for initial accreditation is informed to set-up the facility for an ocular inspection and payment of the prescribed accreditation fees to the Cashier of the DOH, in cash or through postal money order.
1.5 BHFS and NSRC conduct ocular inspection in accordance with NSC technical requirements.
1.6 The BHFS and NSRC recommend approval or disapproval upon inspection.
1.7 The Director of the BHFS signs approval or disapproval of application for accreditation.

If approved, the BHFS registers the health facility as a NSC and issues the corresponding certificate of accreditation to the applicant.
If disapproved, the BHFS sends the findings, recommendations to the applicant who makes the necessary alterations and/ or corrections within fifteen (15) days from the time of inspection. The applicant then requests the BHFS for another inspection. Failure to make necessary corrections of deficiencies within fifteen (15) days after due notice, results to forfeiture of application and accreditation fee.

B. VALIDITY AND EXPIRATION:

1. The Certificate of Accreditation shall have a validity period of three (3) years subject to periodic monitoring.
2. Application for renewal of accreditation not filed within thirty (30) days after expiration shall be treated as a new application.

Annex B. Sample of Claims Summary Form



Republic of the Philippines
PHILIPPINE HEALTH INSURANCE CORPORATION
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email: actioncenter@philhealth.gov.ph

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CSF
(Claim Signature Form)
Revised September 2018

Series #

IMPORTANT REMINDERS:
PLEASE WRITE IN CAPITAL LETTERS AND CHECK THE APPROPRIATE BOXES.
All information required in this form are necessary. Claim forms with incomplete information shall not be processed.
FALSE/INCORRECT INFORMATION OR MISREPRESENTATION SHALL BE SUBJECT TO CRIMINAL, CIVIL OR ADMINISTRATIVE LIABILITIES.

PART I - MEMBER AND PATIENT INFORMATION AND CERTIFICATION

1. PhilHealth Identification Number (PIN) of Member:
2. Name of Member: Last Name / First Name / Name Extension (JR/SR/III) / Middle Name (ex: DELA CRUZ JUAN JR SIPAG)
3. Member Date of Birth: month day year
4. PhilHealth Identification Number (PIN) of Dependent:
5. Name of Patient: Last Name / First Name / Name Extension (JR/SR/III) / Middle Name (ex: DELA CRUZ JUAN JR SIPAG)
6. Relationship to Member: child parent spouse
7. Confinement Period: a. Date Admitted: month day year b. Date Discharged: month day year
8. Patient Date of Birth: month day year
9. CERTIFICATION OF MEMBER:

Under the penalty of law, I attest that the information I provided in this Form are true and accurate to the best of my knowledge.

Signature Over Printed Name of Member — Date Signed: month day year
Signature Over Printed Name of Member's Representative — Date Signed: month day year

If member/representative is unable to write, put right thumbmark. Member/Representative should be assisted by an HCI representative. Check the appropriate box. Member Representative

Relationship of the representative to the member: Spouse Child Parent Sibling Others, Specify
Reason for signing on behalf of the member: Member is incapacitated Other reasons:

PART II - EMPLOYER'S CERTIFICATION (for employed members only)

1. PhilHealth Employer Number (PEN):
2. Contact No.:
3. Business Name: Business Name of Employer
4. CERTIFICATION OF EMPLOYER:

"This is to certify that the required 3/6 monthly premium contributions plus at least 6 months contributions preceding the 3 months qualifying contributions within 12 month period prior to the first day of confinement (sufficient regularity) have been regularly remitted to PhilHealth. Moreover, the information supplied by the member or his/her representative on Part I are consistent with our available records."

Signature Over Printed Name of Employer/Authorized Representative — Official Capacity/Designation — Date Signed: month day year

PART III - CONSENT TO ACCESS PATIENT RECORD/S

I hereby consent to the submission and examination of the patient's pertinent medical records for the purpose of verifying the veracity of this claim to effect efficient processing of benefit payment.
I hereby hold PhilHealth or any of its officers, employees and/or representatives free from any legal liabilities relative to the herein-mentioned consent which I have voluntarily and willingly given in connection with this claim for reimbursement before PhilHealth.

Signature Over Printed Name of Member/Patient/Authorized Representative — Date Signed: month day year

If member/representative is unable to write, put right thumbmark. Member/Representative should be assisted by an HCI representative. Check the appropriate box. Patient Representative

Relationship of the representative to the patient: Spouse Child Parent Sibling Others, Specify
Reason for signing on behalf of the patient: Patient is incapacitated Other reasons:

PART IV - HEALTH CARE PROFESSIONAL INFORMATION

Accreditation No. — Signature Over Printed Name — Date Signed: month day year
Accreditation No. — Signature Over Printed Name — Date Signed: month day year
Accreditation No. — Signature Over Printed Name — Date Signed: month day year

PART V - PROVIDER INFORMATION AND CERTIFICATION

1. PhilHealth Benefits: ICD 10 or RVS Code: 1. First Case Rate 2. Second Case Rate

I certify that services rendered were recorded in the patient's chart and health care institution records and that the herein information given are true and correct.

Signature Over Printed Name of Authorized HCI Representative — Official Capacity/Designation — Date Signed: month day year

Attach filter card sticker in any of these areas

Annex 5. Philhealth Circulars from 2006 - 2011

Philhealth Circular No 34, s-2006: Philhealth Newborn Care Package (NCP)

Republic of the Philippines
PHILIPPINE HEALTH INSURANCE CORPORATION
Citystate Centre, 709 Shaw Boulevard, Pasig City
Healthline 637-9999 *www.philhealth.gov.ph*

PHILHEALTH CIRCULAR
No. 34 , s-2006

TO : **ACCREDITED INSTITUTIONAL AND PROFESSIONAL HEALTH CARE PROVIDERS, MEMBERS OF THE NATIONAL HEALTH INSURANCE PROGRAM AND ALL OTHERS CONCERNED**

SUBJECT : PhilHealth Newborn Care Package (NCP)

The National Health Insurance Program aims to continuously provide its members and dependents with responsive benefits. In line with this objective, the PhilHealth Board has approved Resolution No. 925 series of 2006 providing for the Newborn Care Benefit Package. Guideline for the implementation of said package shall be as follows:

GENERAL RULES

1. The following accredited health facilities shall be the main providers of the NCP:
   a. Hospitals
   b. Non-Hospital Facilities such as Lying-In Clinics, Midwife-managed Clinics, Birthing Homes, Rural Health Units, Ambulatory Surgical Clinics or any other analogous health facilities
2. The NCP utilizes a case payment scheme for reimbursement amounting to Php 1,000 which shall be paid directly to the institutional health care provider
3. This package shall be applicable only to newborns of mothers who are qualified and have complied with PhilHealth requirements before availing of pregnancy-related benefit.
4. Accredited health care providers should be able to provide **all** the necessary services within this package which consists of the following:
   a. Umbilical cord care
   b. Eye prophylaxis
   c. Administration of Vitamin K
   d. Thermal care
   e. First dose of Hepatitis B immunization
   f. Newborn Screening Tests as recommended by the Department of Health
5. The amount of the package is broken down as follows:

Newborn Care Services	Distribution of Case Rate
Eye prophylaxis, umbilical cord care, Vitamin K & thermal care	Php 250
First dose of Hepatitis B immunization	Php 250
Newborn Screening Tests	Php 500

This however, does not allow claims for partial provision of services.

6. Only claims for **complete** newborn care services provided shall be compensated, otherwise, reimbursement to the facility shall be denied. In case of NCP claimed and reimbursed to the facility but later proven to lack the necessary services, the amount reimbursed shall be deducted from the future claims of the facility (health care provider).
7. Room and Board charges shall not be compensated. However, one-day shall be deducted from the 45-day allowance for room and board for dependents of a member. On the other hand, room and board charges may be compensated for newborns admitted/confined due to other conditions/illnesses.
8. Newborns/neonates admitted/confined in a hospital due to other conditions/illnesses may avail of other benefits (including room and board) based on the case type of their diagnosis/illness. Such claim should also include the applicable newborn care services provided for in the package and shall not be considered a separate benefit.
9. This Circular amends the rule on claims payment for newborn care under the Maternity Care Package both in the hospital and non-hospital facilities.

ELIGIBILITY RULES

1. Eligible newborns are those qualified dependents of NHIP members and are born to mothers who satisfy the eligibility requirements to avail of pregnancy related benefit:
   a. An employed/KASAPI member whose premium contributions for at least three (3) months have been paid within the six (6) months prior to the first day of her or his/her dependent's availment shall be entitled to the benefits;
   b. An individually paying member should comply with the rule on sufficient regularity of premium contributions and should have at least nine (9) months or three (3) quarters of premium contributions within the immediate twelve (12) months prior to the availment of the package.
   c. Employed members are required three (3) months of contribution within the immediate six (6) months prior to delivery.
   d. Sponsored members may avail of this benefit within the validity period stated in their PhilHealth Membership Identification Card or Certificate of Eligibility (Form CE1) per PhilHealth Circular No. 3 s. 2005.
   e. OWP members or their dependents may avail of this benefit within the validity period stated in their enhanced Member Data Record (MDR).

CLAIMS FILING

1. A separate claims application using Claim Form 2 must be submitted for this package together with the maternal claim application. The amount for this package shall be indicated in Part I, item 12(C) and Part IV (C) of the said claim form.
2. All claims must be filed within sixty (60) calendar days from the date of discharge.
3. All claim applications for the Newborn Care Package shall be covered by PhilHealth rules on ICD-10.

This Circular shall take effect for all claims with admission dates starting December 1, 2006. All other benefit availment rules inconsistent with these rules are hereby repealed.

(Sgd.) LORNA O. FAJARDO
Acting President and CEO

Date Signed: November 22, 2006

Philhealth Circular No 015, s-2011: Classificatory Guidelines to Philhealth Circlar Nos. 11, 11-A and 11-B series of 2011

Republic of the Philippines
PHILIPPINE HEALTH INSURANCE CORPORATION
Citystate Centre, 709 Shaw Boulevard, Pasig City
Healthline 637-9999 *www.philhealth.gov.ph*

PHILHEALTH CIRCULAR
No. 015, s-2011

TO : ALL PHILHEALTH MEMBERS, ACCREDITED PROVIDERS, PHILHEALTH REGIONAL OFFICES (PhROs), AND ALL OTHERS CONCERNED

SUBJECT : Clarificatory Guidelines to PhilHealth Circular Nos. 11, 11-A and 11-B series of 2011

Pursuant to PhilHealth Circular Nos.11, 11-A and 11-B, series of 2011, the following additional guidelines are being issued for proper implementation.

I. MEDICAL CASES

1) The Newborn Care Package (NCP) shall be composed of the following services and shall be paid a rate of 1,750 pesos.

CODE	DESCRIPTIVE TERMS	AMOUNT
P99432	**A. Provision of essential newborn care** to include all of the following: a. immediate drying of the newborn, b. early skin-to-skin contact, c. cord clamping, d. non-separation of mother/baby for early breastfeeding initiation e. eye prophylaxis, f. Vitamin K administration, g. weighing of the newborn, h. BCG vaccination, i. Hepatitis B immunization (1st dose), and, j. professional fee (including physical examination baby & breastfeeding advice)	1,750 pesos
	B. Newborn Screening Test (NBS)	
	C. Newborn Hearing Screening Test	

a. In cases of incomplete provision of services, the corresponding amounts shall be deducted for the following services:

SERVICES NOT GIVEN	AMOUNT TO BE DEDUCTED FROM CASE RATE (1,750 pesos)
B. Newborn Screening Test (NBS) only	550 pesos
C. Newborn Hearing Screening Test only	200 pesos
BOTH B and C (Newborn Screening Test (NBS)) and (Newborn Hearing Screening Test)	750 pesos

b. Included in the case rate is the allotted 500 pesos for professional fee.

c. The No Balance Billing policy shall still apply as specified.

PHILHEALTH
MA. TERESA A. QUIAOIT
A.O. IV, Chief, RELMS
Date:
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Page 1 of 3

2) In accredited facilities where the required laboratory or diagnostic tests are not available (e.g., Level 1 hospitals with no X-ray, hospitals with no CT scan) *PhilHealth Claim Form 3* should be properly accomplished to support the diagnosis provided.

   a. This will serve as the document to be evaluated by the Corporation for purposes of monitoring compliance to policies and guidelines.
   b. For facilities which have the necessary equipment to perform the needed laboratory tests, diagnostic and ancillary procedures as provided in Circular 11-A, certified photocopy of the result should be attached to the claim application to support the diagnosis. Submission of *PhilHealth Claim Form 3* is optional.

3) For cases with available current Clinical Practice Guidelines (CPG) adopted by societies or as provided by *the World Health Organization* (WHO), facilities may utilize such guidelines aside from those identified in Circular Nos. 11, 11-A and 11-B and may provide other laboratory test (e.g., TUBEX for typhoid fever as per Circular No. 2 s-2009) and ancillary procedures to support the diagnosis. The same amount of case rate will be paid to facility.

II. SURGICAL CASES

1) Cataract procedures covered under the cataract package are the following: **66983**, **66984** and **66987**.

2) As stated in Item VI. A. 5 of Circular No. 11 s-2011, undelivered cases (baby delivered in referral facility) in non-hospital facilities shall be reimbursed 10% of the MCP Package. In these cases, they shall be coded using **P59403**.

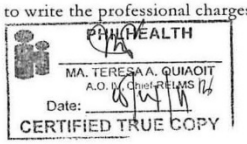
III. GENERAL RULES

1) In the event of death, claims shall be excluded from the package and shall be paid via fee-for-service scheme. As provided in PhilHealth Circular No.18, s-2009, claims shall be considered as:

   a. Case type D in Levels 3 to 4 hospitals,
   b. Case type C in Level 2 hospitals, and;
   c. Case type B in Level 1 hospitals

2) In cases where patients were managed by several doctors (accredited and non accredited), the claim may still be reimbursed in full. The manner of distribution is left with the providers (facility and professional) except in some specified cases. In proper filling of PhilHealth Claim Form 2, there is no need to write the breakdown of amounts in items 11a to 11d.

   a. The total actual hospitalization and PF charges shall **still** be indicated in **11e** Benefit Package (*Actual Charges Column*) and the case rate amount (*PhilHealth Benefit Column*) in the PhilHealth Benefit column.
   b. For item No. 16, there is no need to write the professional charges.



c. Parts II and III of PhilHealth Claim Form 2 (CF2) should be properly accomplished. The provider however may submit an itemized Statement of Account (SOA) as a replacement for the itemized Parts II and III of CF2.
d. All the other information are still required and forms should be properly accomplished for a more efficient processing and monitoring of claims.

All other issuances which are inconsistent with this circular are hereby amended accordingly.

This Circular shall be effective immediately.

DR. REY B. AQUINO
President and CEO
Date signed: 06 Oct 16

PHILHEALTH
MA. TERESA A. QUIAOIT
A.O. IV, CIGI-RELMS
Date:
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PhilHealth
Your Partner in Health
1110061826
OP-S11-44785

Annex 6. Philhealth Circular No. 2018 – 0021: Enhancement of Philhealth Newborn Care Package

Republic of the Philippines
PHILIPPINE HEALTH INSURANCE CORPORATION
Citystate Centre, 709 Shaw Boulevard, Pasig City
Call Center (02) 441-7442 Trunkline (02) 441-7444
www.philhealth.gov.ph

PHILHEALTH CIRCULAR
No. 2018 - 0021

TO : PHILHEALTH ACCREDITED HEALTH CARE INSTITUTIONS (HCI) AND PROFESSIONALS, PHILHEALTH MEMBERS, PHILHEALTH HEAD OFFICE REGIONAL OFFICES and BRANCHES, LOCAL HEALTH INSURANCE OFFICES AND ALL OTHERS CONCERNED

SUBJECT : Enhancement of PhilHealth Newborn Care Package

MASTER COPY Date: 12/14/18 DC: 1495

I. RATIONALE

The National Health Insurance Act of 2013 [Republic Act (RA) 7875 as amended by RA 9241 and RA 10606] declares that "the State shall provide comprehensive health care services to all Filipinos through a socialized health insurance program that will prioritized the health needs of the underprivileged, sick, elderly, persons with disabilities, women and children". Thus PhilHealth aims to provide all Filipinos with mechanism to have financial access to essential health services.

In 2014, The National Comprehensive Newborn Screening System has expanded the screening panel of disorders from six (6) to 28 (and more) disorders pursuant to Department of Health Administrative Order No. 2014-0045 "Guidelines on the Implementation of the Expanded Newborn Screening Program". However, the extra cost of the screening was borne by the families as the current NCP only covers the six-panel test.

Cognizant of its role to provide financial risk protection, PhilHealth through Board Resolution 2365, s-2018 approved the enhanced Newborn Care Package that will cover the expanded newborn screening.

II. OBJECTIVES

This Circular aims to increase the PhilHealth-covered essential health services for the newborns by including the expanded newborn screening among the services under the Newborn Care Package.

III. SCOPE AND COVERAGE

This Circular shall define policies and procedures on the implementation of the Newborn Care Package. This Circular shall apply to all accredited health care institutions (HCI) that perform deliveries and provide newborn care such as hospitals, infirmaries/dispensaries and birthing homes/lying-in clinics.

IV. DEFINITION OF TERMS

Newborn Care Package – a PhilHealth benefit package for essential health services of the newborn during the first few days of life. It covers essential newborn care, newborn screening and hearing screening tests.

Page 1 of 4

V. GENERAL GUIDELINES

A. The Newborn Care Package shall cover infants born in accredited health care institutions and shall be availed of upon delivery.

B. The amount of Package shall be Php 2,950.00 and new Package Code shall be **99460** with the following details:

Newborn Care Package	
Package Code: 99460 **Description:** Initial hospital or birthing center care for evaluation and management of normal newborn infant	
Package Rate:	**Php 2,950.00**
Components:	
Supplies for Essential Newborn Care (ENC) such as Vitamin K, eye ointment, vaccines for hepatitis B and BCG	500.00
Professional Fee	500.00
Expanded Newborn Screening Test (ENBS) ***see Annex A for the list of the complete panel**	1,750.00
Newborn Hearing Screening Test (NHST)	200.00

C. The services for Essential Newborn Care shall include:
1. Immediate drying of the baby;
2. Early skin to skin contact;
3. Timely cord clamping;
4. Non-separation of mother/baby for early breastfeeding initiation;
5. Giving of eye prophylaxis;
6. Vitamin K administration;
7. Weighing of the baby;
8. First dose of hepatitis B Vaccine; and
9. First dose of BCG Vaccine.

D. All services of essential newborn care and expanded newborn screening shall be provided prior to discharge. Claims with incomplete ENC and ENBS services shall be denied.

E. The filter card sticker from the newborn screening kit shall be attached to claims. The filter card number shall be encoded and transmitted along with other requirements of electronic claims submission.

MASTER COPY DC: Date: 12/14/18

F. If newborn hearing screening test is done, documentation shall be required upon submission of claims.

G. Behavioral reflexive tests for hearing such as Tuning Fork test, Penlight Visual examination method and other indigenous methods are not compensable as newborn hearing screening tests under the Newborn Care Package.

H. The newborns should stay in the facility for at least 24 hours after birth except those who warrant immediate referral to a higher-level facility.

I. No Balance Billing (NBB) policy (PhilHealth Circular 2017-006) shall apply.

J. As stated in PhilHealth Circular 09, s-2014 (ACR Policy No. 3 -Additional List of Medical Conditions for Hospitals, New Rates for Selected Case Rates in Primary Care Facilities, Infirmaries-Dispensaries, and Clarification of Existing Rules on All Case Rates), newborns

delivered in hospitals and managed for other morbid conditions (i.e. newborn sepsis, congenital pneumonia) may also claim for NCP as second case rate for health services provided to the newborn.

VI. CLAIMS FILING

A. Health Care Institutions shall submit the claims electronically according to the PhilHealth e-claims guidelines.

B. The eligibility of either of the parents as principal members to avail of PhilHealth benefits is automatically conferred to the newborn. The HCI shall check their eligibility through Claim Eligibility Web Service (CEWS).

C. If eligible, properly and correctly accomplished PhilHealth Membership Registration Form (PMRF) shall be attached to the claim for updating of the member's profile. Claims without the PMRF shall be returned.

D. The Newborn Screening (NBS) filter card number shall be encoded and transmitted as part of electronic claims while the filter card sticker shall be attached to the lower right portion of the Claim Signature Form (CSF) as illustrated on Annex B. Claims that lack any of the two shall be denied. The filter card number shall be verified with the Newborn Screening Reference Center (NSRC). Claims with unregistered filter card number shall be denied while those with inconsistencies shall be returned to the facility.

E. If the newborn hearing screening test is done, the result of the test shall be attached to the claim (Annex C). Likewise, the result of the test (pass or refer) shall be encoded in the electronic claim form. Claims without the said results shall automatically have a deduction of Php 200 which is equivalent to the NHST component.

MASTER COPY Date: 12/4/19 DC:

F. Starting July 1, 2019 (date of admission) claims with Newborn Hearing Screening Test shall also have an attached copy of Newborn Hearing Registry Card (Blue Form) as shown on Annex E. The registry number shall also be included during submission of electronic claims. Claims without any of them shall have a deduction of Php 200 which is equivalent to the NHST component.

G. The documents required as attachment for claims are listed on Annex F of this Circular.

H. Processing of claims for confinement abroad shall follow the existing rules and guidelines. The newborn screening filter card number and the newborn hearing screening registry number shall no longer be required for these types of claims.

VII. TRANSITION PERIOD FOR 6-PANEL NEWBORN SCREENING

Newborn Care Package with the **6-panel newborn screening** shall be claimed using the package code of **99432**. Claims shall be paid with the old rate (Php 1,750.00 or Php 1,550.00 whichever is applicable). However, starting **May 1, 2019** all infants born in accredited facilities shall be tested for expanded newborn screening panel. Consequently from thereon, claims with 6- panel test shall be denied. For clarification, several scenarios are elucidated in Annex F of this Circular.

VIII. MONITORING AND EVALUATION

The benefits delivery shall be anchored on PhilHealth Health Care Provider Performance Assessment System. All beneficiaries of the package who received newborn screening test shall be registered by the providers in the Newborn Screening Registry maintained by the NSRC while those with claims for newborn hearing screening shall be registered in the newborn hearing screening registry. The said registries shall be used as reference during monitoring.

IX. REPEALING CLAUSE

This Circular amends Sections VII and X of PhilHealth Circular 25-2015 (Social Health Insurance Coverage and Benefits of Women About to Give Birth Revision 1).

Provisions of other previous issuances inconsistent with this PhilHealth Circular are hereby amended, modified or repealed accordingly. All other rules and guidelines not contrary to this Circular shall remain in full force and in effect.

X. EFFECTIVITY

This circular shall take effect after 15 days following its publication in any newspaper of general circulation. It shall be deposited thereafter with the National Administrative Register at the University of the Philippines Law Center.

XI. ANNEXES

Annex A - List of Disorders Included in the Expanded Newborn Screening Panel

Annex B - Sample Claim Signature Form (CSF) with Newborn Screening Filter Card Sticker

Annex C - Sample of Newborn Hearing Screening Results

Annex D - Sample of Newborn Hearing Screening Registry Card

Annex E - Table of Scenarios During Transition Period for the 6-Panel Newborn Screening Test

Annex F - Summary of Documents Required as Attachment to Newborn Care Package Claims

ROY B. FERRER, MD, MSc
Acting President and CEO

Date signed: 12/13/18

MASTER COPY
DC: Date: 12/14/18

Annex A. List of Disorders Included in the Expanded Newborn Screening Panel (as of August 28, 2018)

Disorder Group	Disorder	Abbreviation	Metabolite Tested
Endocrine Disorder	Congenital Hypothyroidism	CH	Thyroid Stimulating Hormone (TSH)
	Congenital Adrenal Hyperplasia	CAH	17-hydroxy- progesterone (17 a-OHP)
Amino Acid Disorder	Homocystinuria	HCY	Methionine
	Hypermethioninemia/ Methionine Adenosine Transferase Deficiency	MAT	Methionine
	Maple Syrup Urine Disease	MSUD	Leucine
	Phenylketonuria	PKU	Phenylalanine
	Tyrosinemia Type I, II		Tyrosine
Fatty Acid Disorder	Carnitine Palmioyltransferase I Deficiency	CPT 1	Carnitine Palmioyltransferase I
	Carnitine Palmioyltransferase II Deficiency	CPT 2	Hexadecanoylcarnitine
	Carnitine Uptake Deficiency	CUD	Free carnitine
	Glutaric Acidemia Type II	GA II	Butyrylcarnitine
	Long Chain Hydroxyacyl- CoA Dehydrogenase Deficiency	LCHAD	Hydroxyhexadecanoylcarnitine (AC16OH)
	Medium Chain Hydroxyacyl-CoA Dehydrogenase Deficiency	MCAD	Octanoylcarnitine
	Short Chain Hydroxyacyl- CoA Dehydrogenase Deficiency	SCAD	Butyrylcanitine
	Very Long Chain Hydroxyacyl-CoA Dehydrogenase Deficiency	VLCAD	Tetradecanoylcarnitine
Organic Acid	3- Methylcrotnyl CoA Carboxylase Deficiency	3MCC	Hydroxyisovalerylcarnitine (AC5- OH)
	Glutaric Acidemia Type I	GA I	Glutarylcarnitine
	Isovaleric Acidemia	IVA	Isovalerylcarnitine
	Methylmalonic Acidemia	MMA	Propionylcarnitine
	Multiple Carboxylase Deficiency	MCD	Hydroxyisovalerylcarnitine
	Propionic Acidemia	PA	Propionylcarnitine
Urea Cycle Defect	Citrullinemia	CIT	Citrulline
Cystic Fibrosis	Cystic Fibrosis	CF	Immunoreactive Trypsine (IRT)
Hemoglobinopathies	Alpha Thalassemia	HgB	Hemoglobin
	Beta Thalassemia		
	Hemoglobin C		
	Hemoglobin D		
	Hemoglobin E		
Biotinidase Deficiency	Biotinidase Deficiency	BTND	Biotinidase
Others	Galactosemia	GAL	Total Galactose
	Glucos-6- Phosphate Dehydrogenase Deficiency	G6PD Def	G6PD enzyme activity

Source: Newborn Screening Reference Center

Philhealth Circular No. 20, s-2007: Amendment to Circular No. 34 s 2006

Republic of the Philippines
PHILIPPINE HEALTH INSURANCE CORPORATION
Citystate Centre, 709 Shaw Boulevard, Pasig City
Healthline 637-9999 *www.philhealth.gov.ph*

PHILHEALTH CIRCULAR
No. 20, s-2007

TO : **ACCREDITED INSTITUTIONAL AND PROFESSIONAL HEALTH CARE PROVIDERS, MEMBERS OF THE NATIONAL HEALTH INSURANCE PROGRAM AND ALL OTHERS CONCERNED**

SUBJECT : **AMENDMENT TO PHILHEALTH CIRCULAR NO. 34 s.2006 PHILHEALTH NEWBORN CARE PACKAGE (NCP)**

Pursuant to approved PhilHealth Board Resolution No. 1060 series of 2007 amending PhilHealth Board Resolution No. 925 s.2006 the following are guidelines on the implementation of NCP:

GENERAL RULES

1. The package shall cover all eligible newborn-dependents delivered in all accredited health facilities including non-hospital maternity health care providers.
2. Services covered shall include administration of BCG vaccine and resuscitation of the newborn. The amount of the package however shall remain at P1,000.
3. It is reiterated that the health care facility should be able to provide all the required services covered by the package. In case the facility was not able to provide the complete services, claims from the said facility shall not be compensated. This however, shall not prohibit payment to members within the amount of the package item enumerated in Circular No. 34 s.2006 provided that Official Receipt/s are attached to the claim application.
4. To qualify as service providers for this package, currently accredited facilities and those applying for initial, renewal and re-accreditation are required to submit a photocopy of Newborn Screening Facility (NSF) certificate issued by the Department of Health (DOH) or Newborn Screening Reference Center (NSRC) to the Accreditation Department or Accreditation Section of PhilHealth Regional Offices (PROs) on or before December 31, 2007. All claims of PhilHealth accredited facilities for NCP with admission beginning January 1, 2008 that are not certified by DOH or NSRC as NSF shall not be reimbursed.
5. Newborn Screening (NBS) is ideally performed after twenty-four hours of life but not later than three (3) days from complete delivery of the newborn. As such, claims for NCP within the said period shall be compensated. However, for newborns placed in intensive care to ensure survival, premature and sick newborns, they may be exempted from the three-day requirement but should be tested within seven (7) days of age. Official Receipt/s for NBS dated within the same period (even after discharge of patient/ newborn) shall be covered by the package.

CLAIMS FILING

1. The facility should indicate the **filter collection card number** of the NBS specimen collection form in the Part IV (C) item no. 3 of the said claim form. The said claim form shall be returned to the facility in case the facility is not able to indicate the said number.

To illustrate:

C. Others

1. Eye prophylaxis, umbilical cord care, Vitamin K, thermal care, administration of BCG vaccine & resuscitation of the newborn
2. 1st dose of Hepatitis B immunization
3. Newborn Screening Test ***(filter collection card number)***

2. All services covered by the package should be enumerated in the Part IV (C) of the said claim form as shown above.
3. To facilitate speedy processing of claims it is reiterated that Claim Forms 1 and 2 shall be submitted together with maternal application within the prescribed period.
4. All claim applications for NCP shall be coded using RVS code **99432**

CODE	DESCRIPTIVE TERM	RVU
99432	Normal Newborn Care	Package

5. PhilHealth rules on ICD-10 shall also apply for this package.
6. Requirements for NCP claim applications shall include:

   6.1 duly accomplished Forms 1 and 2
   6.2 certificate of live birth
   6.3 clear copy of Member Data Record
   6.4 proof of premium payment

This Circular shall take effect for all claims with admission dates starting January 1, 2008. All other benefit availment rules inconsistent with these rules are hereby repealed.

(Sgd.) LORNA O. FAJARDO
Acting President and CEO

Date signed: December 12, 2007

Annex C. Sample of Newborn Hearing Screening Official Result

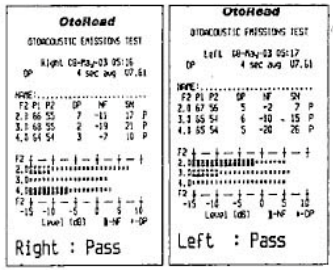
Form No. _____

NAME OF NEWBORN HEARING SCREENING CENTER
ADDRESS, CONTACT NO., EMAIL

OTOACOUSTIC EMISSIONS (OAE)
OR
AUTOMATED AUDITORY BRAINSTEM RESPONSE (AABR)
Hearing Screening Results

Name of Patient: _____ Age/Sex: _____
Address & Tel. No.: _____ Date of Birth: _____
Referring Doctor: _____ Date Tested: _____ NHSRC Registry No.: _____

The hearing screening test was done using otoacoustic emissions (OAE) *or automated auditory brainstem response* test. Below are the results, please do not hesitate to get in touch with us if you have any question regarding the screening procedure or the results.



	* PASS	**REFER
RIGHT EAR:	X	
LEFT EAR:	X	

COMMENTS: _____

MASTER COPY DC: ncs Date: 12/14/18

*PASS: Means that the hearing pathway from the ear canal to the cochlea is intact. This usually suggests normal development of speech and language unless there are other problems.

**REFER: Means that further evaluation and testing is needed to make sure that there is no hearing impairment. Earwax or a baby who is very active during the test may lead to a 'REFER' result. We recommend a repeat screen in 1-3 months time.

PLEASE SHOW THE RESULTS TO YOUR PHYSICIAN. Even if your baby passed the test, your child's doctor will decide whether a re-screen is needed (if your child is high risk for hearing loss) or if further evaluation is required.

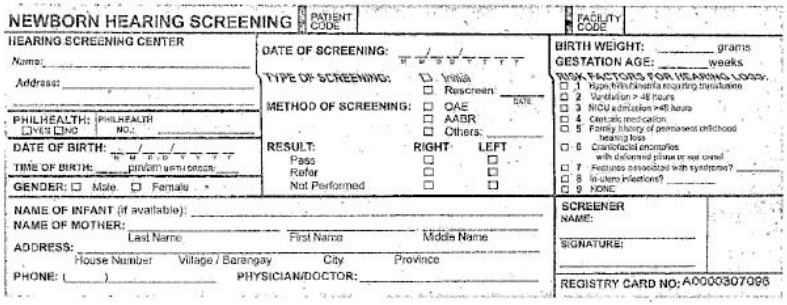
PLEASE BE ADVISED THAT IT IS IMPORTANT TO CONSULT YOUR CHILD'S DOCTOR IF THERE IS ANY CHANGE OR PROBLEMS REGARDING YOUR CHILD'S HEARING.

_____ Consultant
Section of Audiology

_____ Screener
(Signature Over Printed Name)

Reference: Revised Manual of Operations of RA 9709, 2016

Annex D. Newborn Hearing Screening Reference Card



NEWBORN HEARING SCREENING

PATIENT CODE

FACILITY CODE

HEARING SCREENING CENTER
Name:
Address:

PHILHEALTH: ☐YES ☐NO PHILHEALTH NO.:

DATE OF BIRTH: M M / D D / Y Y Y Y

TIME OF BIRTH: (HH:MM) BIRTH ORDER

GENDER: ☐ Male ☐ Female

DATE OF SCREENING: M M / D D / Y Y Y Y

TYPE OF SCREENING: ☐ Initial ☐ Rescreen: DATE

METHOD OF SCREENING: ☐ OAE ☐ AABR ☐ Others:

RESULT:	RIGHT	LEFT
Pass	☐	☐
Refer	☐	☐
Not Performed	☐	☐

BIRTH WEIGHT: _____ grams
GESTATION AGE: _____ weeks

RISK FACTORS FOR HEARING LOSS:
☐ 1 Hyperbilirubinemia requiring transfusion
☐ 2 Ventilation > 48 hours
☐ 3 NICU admission >48 hours
☐ 4 Ototoxic medication
☐ 5 Family history of permanent childhood hearing loss
☐ 6 Craniofacial anomalies with deformed pinna or ear canal
☐ 7 Features associated with syndrome? _____
☐ 8 In-utero infection? _____
☐ 9 NONE

NAME OF INFANT (if available): _____
NAME OF MOTHER: Last Name / First Name / Middle Name
ADDRESS: House Number / Village / Barangay / City / Province
PHONE: (____) _____ PHYSICIAN/DOCTOR: _____

SCREENER
NAME:
SIGNATURE:

REGISTRY CARD NO: A0000307096

MASTER COPY
DC: ____ Date: 12/14/18

Annex E. Table of Examples to Illustrate Transition Period for the 6-Panel Newborn Screening Test

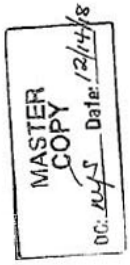
Scenario/Example:

Date of Publication of the Circular: December 20, 2018
Date of Effectivity of the Circular: January 5, 2019 (fifteen days after publication)
Last day of Transition Period: April 30, 2019

Newborn Services Performed	Date of Birth/Admission	Claims Filing	Remarks
• Complete Essential Newborn Care • Expanded Newborn Screening • Newborn Hearing Screening Test	December 20, 2018	File as Package Code 99432	Circular though published is not yet effective.
• Complete Essential Newborn Care • 6-panel Newborn Screening • Newborn Hearing Screening Test	December 20, 2018	File as Package Code 99432	Circular though published is not yet effective.
• Complete Essential Newborn Care • Expanded Newborn Screening • Newborn Hearing Screening Test	January 5, 2019	File as 99460	Circular is effective by January 5, 2019.
• Complete Essential Newborn Care • 6-panel Newborn Screening • Newborn Hearing Screening Test	January 5, 2019	File as 99432	Transition Period Although Circular is effective, only 6-panel NBS was done.
• Complete Essential Newborn Care • 6-panel Newborn Screening • Newborn Hearing Screening Test	April 30, 2019	File as 99432	Last day of Transition Period Only 6-panel NBS was done.
• Complete Essential Newborn Care • 6-panel Newborn Screening • Newborn Hearing Screening Test	May 1, 2019	Deny claim	Claims with 6-panel test shall be denied. All newborns should be tested for expanded NBS starting May 1, 2019.
• Complete Essential Newborn Care • Expanded Newborn Screening • Newborn Hearing Screening Test	May 1 , 2019	File as 99460	All newborns should be tested for expanded NBS starting May 1, 2019

Annex F. Summary of Documents Required as Attachment to Newborn Care Package Claims

1. Claims Signature Form (CSF) with attached Filter Card Sticker
2. Properly and correctly accomplished PhilHealth Membership Registration Form (PMRF)
3. Claim Form 2 – If applicable
4. Statement of Account
5. Result of Newborn Hearing Screening Test – If applicable
6. Newborn Hearing Screening Registry Card (Blue Form) – If applicable, starting June 1, 2019



Annex 7. Implementation of the Expanded Newborn Screening Program

Administrative order 2014 – 0045: Guidelines on the Implementation of the Expanded Newborn Screening Program

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

NOV 19 2014

ADMINSTRATIVE 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.

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Fax: 743-1829; 743-1786 • URL: http://www.doh.gov.ph e-mail: osec@doh.gov.ph

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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.

Site renovations/preparations, procurement of equipment and reagents, hiring and training of personnel, upgrading of database, preparation of manuals and protocols,

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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, GAI , 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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JN S. DELA CRUZ
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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.

ENRIQUE T. ONA, MD
Secretary

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RECORDS SECTION
Department of Health

Administrative Order 2014 – 0045 – A: Amendment to AO 2014-0045 Guidelines on the Implementation of the Expanded Newborn Screening Program

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAR 29 2019

ADMINISTRATIVE ORDER
No. ~~2019-~~ 2014-0045-A

SUBJECT: **Amendment to Administrative Order No. 2014-0045: Guidelines on the Implementation of the Expanded Newborn Screening Program**

Pursuant to Section 11 of Republic Act No. 9288, otherwise known as the Newborn Screening Act of 2004, the Advisory Committee on Newborn Screening (ACNBS) shall review and recommend the newborn screening (NBS) fee to be charged by the Newborn Screening Center (NSCs) in order to ensure that NBS will be accessible to all newborns.

During the meeting of the ACNBS held last 04 October 2018, the price adjustment in the expanded newborn screening (ENBS) fee of One Thousand Seven Hundred Fifty Pesos (Php1, 750.00) has been approved. The said price will apply to all new NBS filter cards purchased from the NSCs upon effectivity of this Order. In view of this, the following provision of Administrative Order No. 2014-0045 dated November 19, 2014 is hereby amended:

FROM:
VI. Specific Guidelines/Implementing Mechanism
D. Budget Source
1. **The NBS Fee**
   a. The cost of the tests shall be as follows (*Per recommendation of the ACNBS 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 Php 550.00 shall be covered by PhilHealth and the balance shall be an out-of-pocket expense of the family.

TO:
VI. Specific Guidelines/Implementing Mechanism
D. Budget Source
1. **The NBS Fee**
   a. The cost of the tests shall be as follows (*Per recommendation of the ACNBS on October 04, 2018)*:
      Option 1 (6 disorders) - Php550.00
      Option 2 (Expanded Newborn Screening) - Php1,750.00.

   b.For PhilHealth members, the total cost shall be covered by PhilHealth (*Per PhilHealth Circular 2018-0021* on *Enhancement of Newborn Care Package*):
      Option 1 (6 disorders) - Php 550.00
      Option 2 (Expanded Newborn Screening) – Php 1750. 00

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1113, 1108, 1135
Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: fduque@doh.gov.ph

Option 1 (6 disorders) shall be offered until April 30, 2019 only. Effective May 1, 2019, all infants born in accredited facilities shall be tested for expanded newborn screening panel (Option 2) only.

As thus amended, all other provisions of Administrative Order No. 2014-0045 shall remain in full force and in effect.

This order shall take effect fifteen (15) days after publication in the official gazette or newspaper of general publication.

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

Annex 8. Administrative Order 2020 – 052 Revised Guidelines on the Implementation of the Expanded Newborn Screening Program

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 27 2020

ADMINISTRATIVE ORDER
NO. 2020-0052

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

I. BACKGROUND/RATIONALE

Republic Act 9288, otherwise known as "the Newborn Screening Act of 2004, provides for the establishment of a national comprehensive newborn screening system that includes (i) education of relevant stakeholders; (ii) screening, recalling and diagnosis of patients; (iii) provision of medical/dietary/surgical management to address the untoward consequences of heritable conditions when left untreated; and (iv) evaluation activities to assess long term outcome, patient compliance and quality assurance of short term and long term follow-up. The principles being carried out by the Republic Act 9288 of universality, inclusivity, and person-centeredness are the same principles that Department of Health (DOH) ushers in through Republic Act 11223 or the Universal Health Care (UHC) Act.

The Expanded Newborn Screening (ENBS) as an option to the NBS basic 6-test was implemented in November 2014 through the issuance of DOH Administrative Order (AO) No. 2014-0045. Further, the National Policy and Strategic Framework on Expanded Newborn Screening for 2017-2030, which was released on November 05, 2018 through the issuance of DOH AO No. 2018-0025, outlined the shift to ENBS and the provision of continuing care for confirmed patients. The ENBS Fee was later increased from Php1,550 to Php1, 750 in March 2019 by an amendment to AO No. 2014-0045-A. The ENBS Fee augments other services in addition to screening, such as confirmatory tests for the metabolic conditions and hemoglobinopathies and life-saving management of newborns diagnosed with metabolic disorders. PhilHealth worked on the full coverage of the ENBS in the Newborn Care Package and released the Circular No. 2018-0021 on Enhancement of Newborn Care Package which includes the coverage of the ENBS Fee of Php1, 750.00.

With the above-mentioned developments and thrust of the program towards full shift to ENBS, this Order shall serve as reference for the full implementation of the ENBS to ensure the continuity and sustainability of quality testing, follow-up services and management of diagnosed newborn infants in the country with the provision of guidelines on the transition to full expanded screening, on the establishment and operation of Center for Human Genetic Services, and on the allocation of a portion of the ENBS Fee to augment the cost of treatment and management of patients.

II. OBJECTIVES

To update the guidelines on the following:

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 Direct Line: 711-9501
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1. Implementation of the Expanded Newborn Screening Program;
2. Expansion of the National Comprehensive Newborn Screening System (NCNBSS) with the establishment of the Centers for Human Genetics Services (CHGS).
3. Allocation and utilization of a portion of the ENBS funds for the operation of the CHGS and for the management (diagnostic and therapeutic) of patients.

III. SCOPE OF APPLICATION

This Order shall apply to all DOH-Centers for Health Development (CHD), Ministry of Health (MOH) Bangsamoro Autonomous Region in Muslim Mindanao (BARMM), Newborn Screening Centers (NSCs), Newborn Screening Reference Center (NSRC), Institute of Human Genetics, Newborn Screening Facilities (NSFs), and all other agencies and stakeholders concerned in the implementation of the newborn screening program.

IV. DEFINITION OF TERMS

1. *Advisory Committee on Newborn Screening (ACNBS)* - refers to the body created as an integral part of the Office of the Secretary of the DOH to ensure sustained inter-agency collaboration. It is tasked, among others, to review and recommend the standard NBS Fee to be charged by NSCs.

2. *Acute Crisis* - refers to acute episode of illness caused by accumulation of toxic metabolites which may be precipitated by catabolic stress such as infections, fasting, or events surrounding the perinatal period. This may manifest with a variety of symptoms depending on the specific disorder, but may involve poor feeding, altered conscious state, seizures, acidosis or ketosis, respiratory distress and circulatory failure.

3. *Center for Human Genetic Services (CHGS)*- refers to a facility that covers island-wide services (Luzon, Visayas Mindanao) and facilitates comprehensive clinical evaluation, appropriate management (diagnostic and therapeutic), and genetic counseling services to families or individuals with genetic conditions.

4. *Confirmatory Center* - refers to a facility identified by the DOH to be part of the National Comprehensive Newborn Screening System-Treatment Network, equipped to do confirmatory testing to ensure the accuracy of screening results.

5. *Dietary Supplements* - refer to vitamins, minerals, amino acids or other nutrients intended to provide nutrition, enhance the removal of accumulated toxins or facilitate the function of a metabolic process (e.g. carnitine for organic acidurias and carnitine uptake defect; and biotin for biotinidase deficiency).

6. *Genetic Services* - refer to services (i.e. genetic counseling, metabolic nutrition counseling, clinical consults for evaluation and management reviews, etc.) provided to patients confirmed to have metabolic disorders, birth defects and other genetic disorders.

7. *Goods* - refer to medications, medical food, dietary supplements, and highly specialized medical supplies.

8. *Medical Food* - refers to food used for therapeutic purposes specially formulated and intended for the dietary management of a disorder that has distinctive nutritional needs that cannot be met by normal diet alone (e. g. phenylalanine-free milk).

9. *Medications* - refer to medicines that may or may not be available commercially but essential for treatment; thus, prescribed by the pediatrician or specialist to address specific medical issues of patients with metabolic disorders. Treatment quantity and duration may vary according to the prescription of the pediatrician or specialist.

10. 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.

11. *National Institutes of Health-Institutes 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 diagnostics services pertinent to the management of heritable conditions.

12. *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 the DOH, and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.

13. *Newborn Screening Continuity Clinic (NBSCC)* - 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, equipped to facilitate continuity of care of confirmed patients in its area of coverage.

14. *Newborn Screening Facilities* (NSFs) - refers to institutions (i.e. hospitals, birthing facilities, sanitaria, infirmaries, rural health units and health centers) offering newborn screening services such as, but not limited to, motivation of parents, collection of blood sample and recall.

15. *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 (ACNBS).

16. *PhilHealth Enhanced Newborn Care Package* (NCP) - refers to the PhilHealth benefit package released on December 21, 2018, which includes the full coverage of the ENBS fee of Php1,750 in the NCP.

V. GENERAL GUIDELINES

A. Expanded Newborn Screening shall be offered in all NSFs.

B. The number of disorders in the expanded newborn screening panel shall be twenty-eight (28) and more 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.

C. The NCNBSS-Treatment Network for the expanded newborn screening shall be maintained in strategic areas of the country.

   a. Confirmatory centers that provide confirmatory testing following a positive screen and follow-up of diagnosed individuals shall be maintained and the list of confirmatory centers to be provided by NSRC.
      Confirmatory Testing Fund allocation, from the NSCs and CHD shares on portion of the ENBS Fee, shall be used for confirmatory testing of conditions included in the newborn screening panel.
   b. The CHGS shall be established and will cover island-wide services (Luzon, Visayas, and Mindanao). It shall facilitate comprehensive clinical evaluation, appropriate diagnostic and therapeutic management, and genetic counseling services to families or individuals confirmed to have a disorder included in the ENBS panel.
   c. Newborn Screening Continuity Clinics (NBSCCs) established as per AO No. 2014-0035 shall be added in strategic areas of the country to facilitate and increase access to long term care of patients confirmed through newborn screening.
   d. Experts committees on ENBS panel of disorders shall be created and maintained to provide new information on the disorders, participate in the review of datasets and cutoffs of the disorders, propose research agenda and recommend inclusion of new disorders.

D. Information, education, and communication on the expanded screening and the disorders included shall be made available to health professionals, parents, and the general public at all NSCs, DOH-Central Office, DOH-CHDs, MOH-BARMM, and Newborn Screening Facilities through multi-media in collaboration with the DOH-HPCS and NSRC.

E. Newborn Screening Center preparations shall include laboratory renovations to meet accreditation standards, 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 and shall be undertaken in line with the strategies enumerated in the National Policy and Strategic Framework on Expanded Newborn Screening for 2017-2030.

VI. SPECIFIC GUIDELINES

A. Establishment of CHGS

1. National Institutes of Health-Institute of Human Genetics (NIH-IHG) shall establish the CHGS of the Newborn Screening Program.

2. The NIH-IHG shall have administrative and operational oversight of all CHGS.

3. The NIH-IHG shall serve as the CHGS for Luzon. It shall establish satellite CHGS in Visayas, Mindanao and other centers in the future.

4. The CHGS shall be manned by a core team composed of clinical geneticist, pediatrician or family physician, nurse, dietitian/nutritionist, pharmacist, genetic counselors, psychologists, social worker and administrative staff.

B. 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 Department of Health, through the Disease Prevention and Control Bureau-Children's Health Development Division (DPCB-CHDD), shall be the lead agency in the implementation of ENBS. Its roles and responsibilities are stated in Section 13 of the Implementing Rules and Regulations of RA 9288. The DPCB-CHDD shall also be responsible in reviewing/updating the guidelines periodically at least 3 years or sooner if there are new developments in the program.
b. The Health Promotion and Communications Service (HPCS), in coordination with the NSRC, shall be responsible for advocacy and information dissemination on expanded newborn screening to the communities throughout the country.
c. The Health Facilities and Services Regulatory Bureau (HFSRB) shall ensure health facilities applying as newborn screening facilities shall comply to the minimum regulatory standards set by the DOH in the provision and delivery of quality maternal and newborn care services. Further, it shall enforce the fines and other penalties as contained in issuances concerning ENBS fees and the like.
d. The Health Facility Development Bureau (HFDB) shall assist in the identification of facilities or institutions that will qualify as the Newborn Screening Centers in the other parts of the country where the services of such will contribute in the provision of the comprehensive newborn screening services. It shall integrate and update relevant aspects of establishing and developing NSCs all over the country in the Health Facility Development Plan sensitive to the needs of the country. Further, the HFDB shall provide technical inputs in the further development of these NSCs in various joint workshops of the NSRC and DOH.

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2. ***Centers for Health Development shall:***

   a. Assist in the implementation of expanded newborn screening;
   b. Collaborate with relevant stakeholders; and
   c. Allocate funds for expenses related to monitoring of patients and adherence to medical management and continuity care where needed.

3. ***Philippine Health Insurance Corporation (PhilHealth) shall:***

   a. Include the full coverage of the ENBS in the PhilHealth Newborn Care Package.
   b. Issue circulars defining the new policies and procedures on the enhancement of the Newborn Care Package, particularly on ENBS.
   c. Revise the coverage of the current Newborn Care Package based on the recommendations from the Health Technology Assessment Council.

4. ***Newborn Screening Facilities shall:***

   a. Ensure that expanded newborn screening is offered; and
   b. Provide 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.

5. ***Newborn Screening Reference Center shall:***

   a. Provide the guidelines for the establishment of the NSCs, NBSCCs, CHGS, and other health facilities that will be relevant to the implementation of the ENBS Program, to include but not limited to personnel requirements (for hiring and renewal) and laboratory accreditation requirements;
   b. Define the testing and follow-up protocols for the additional disorders;
   c. Maintain an external laboratory proficiency testing program;
   d. Integrate the additional disorders in its case registries and national testing database;
   e. Assist in training activities in all aspects of the NBS program;
   f. Handle the legal requirements for the remittance, allocation and transfer of fund with NSCs and with NIH-IHG;
   g. Determine the appropriate allocation of funds for confirmatory testing and management/treatment based on the prevailing costs in coordination with DOH; and
   h. Conduct program monitoring in coordination with the Department of Health.

6. NIH-IHG shall:

a. Establish and oversee the operations of CHGS;
b. Facilitate the procurement and distribution of goods needed by the NSCs and the CHGS;
c. Submit to NSRC the annual funding proposal for the procurement and distribution of specific goods needed and the operations of CHGS; and
d. Submit quarterly reports to NSRC on procured and required medicines for CHGS.
e. Submit consolidated reports of CHGS to NSRC.

7. Centers for Human Genetic Services shall:

a. Facilitate comprehensive clinical management and genetic. counseling services for families and individuals;
b. Assist NSCs, NSFs, and NBSCCs in the acute and long term management of patients;
c. Serve as the central repository of medical foods, orphan drugs and products and other treatment needs not readily available locally and/or commercially;
d. Coordinate the distribution of medical food, supplies, drugs to NSCs and NBSCCs;
e. Conduct research that shall contribute evidence-based data for directing strategic future plans of the National Comprehensive Newborn Screening System program;
f. Collaborate with NIH-IHG—in developing management guidelines and other related advocacy materials targeting relevant stakeholders;
g. Submit periodic reports to NIH-IHG. and
h. Assists NSRC in its capacity building among health personnel of NBSCCs, among others;

8. Newborn Screening Centers shall:

a. Ensure that personnel, laboratory space, equipment and supplies needed for the implementation of the expanded newborn screening are in place;
b. Ensure that the mechanism for ordering and payment of expanded newborn screening service is in place;
c. Strictly follow the prescribed guidelines of good laboratory practices;
d. Establish an appropriate financial and inventory system that shall ensure effective and efficient distribution of goods to patients with metabolic disorders in acute crisis;
e. Ensure that patients identified positive in any of the disorders are followed up, confirmed, and referred to specialists for initial management;
f. Remit funds to NSRC for treatment and for CHGS;

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g. Allocate funds for monitoring, appropriate diagnostic and therapeutic management, and confirmatory of patients where necessary;
h. Coordinate with CHGS on the management of patients needing further diagnosis and/or management; and
i. Endorse confirmed patients to the NBSCCs for continuity care.

9. Newborn Screening Continuity Clinics (NBSCCs) shall:

a. Facilitate continuous care of confirmed positive patients;
b. Provide long-term follow-up care activities related to improving care delivery, including engagement of affected individuals and their families;
c. Ensure periodic distribution of goods to patients seen at the continuity clinic;
d. Ensure proper storage of goods;
e. Maintain buffer stock and record of goods;
f. Coordinate with the CHGS on provision of long-term management of their patients, including supply of medical food and orphan drugs/products;
g. Provide monitoring data and surveillance of patients to NSRC and DOH for policy development;
h. Schedule genetic counseling sessions for the parents and other family members, either face-to-face or Telegenetic counseling;
i. Submit periodic reports to CHGS on the agreed indicators for quality care of patients; and
j. Submit quarterly reports to NSRC.

C. Budget Source

1. *The NBS Fee*

a. The adjusted ENBS Fee shall be Php1, 750.00 (Per recommendation of the Advisory Committee on Newborn Screening on October 04, 2018).
b. For PhilHealth members the total ENBS Fee of Php1,750.00 shall be covered.
c. ENBS 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-Health Facilities and Services Regulatory Bureau (HFSRB. The administrative fines shall be imposed on health facilities that collect more than the maximum allowable NBS fees (DOH AO 2008-0026-A):
   i. 1st offense - Warning
   ii. 2nd offense - Administrative fine of fifty thousand pesos (P50, 000)

iii. 3rd offense - Administrative fine of one hundred thousand pesos (P100, 000)

2. *Usage of the NBS Fee*

a. As stated in Section 22 of the Implementing Rules and Regulations of RA 9288, "Guidelines on the usage of funds, as approved by the ACNBS, shall be formulated by the NIHP and DOH. The NBS fee shall be applied to, among others, testing costs, education, sample transport, follow-up and reasonable overhead expenses."

b. The treatment fund is a portion of ENBS fee that shall be allocated to augment the cost of treatment and management of patients.

c. The NSRC shall prepare a Memorandum of Agreement (MOA) with NSCs and NIH-IHG for the allocation and transfer of funds from NSC which shall in turn be transferred to IHG for the procurement of medicines, medications, and medical/surgical management for patients from all NSCs and the operation of CHGS.

d. NSCs shall allot:
   i. ₱200 per patient screened intended for treatment fund, and facilitate quarterly transfer of treatment fund to NSRC based on actual collection; and
   ii. ₱30 per patient screened intended for operations of the CHGS, and facilitate quarterly transfer of fund to NSRC based on actual collection. The budget for the CHGS operations shall include Personnel Services, Maintenance and Office Operation Expenses and Capital Outlay (e.g. space rental/renovation, office equipment, etc.).

e. The Treatment Fund shall augment expenses for treatment of patients with a confirmed metabolic disorder who underwent ENBS. These expenses shall be limited to medications, dietary supplements, medical food, and highly specialized medical supplies. The list shall be provided by the NIH-IHG;

f. The Treatment Fund support shall also be provided for initial (one-time) acute crisis management. This shall be limited to emergency medical procedures (e.g. peritoneal dialysis, central line placement), medications, medical food, dietary supplements, and highly specialized medical supplies. This shall not be convertible to cash;

g. The assistance to patients shall be subject to availability of funds; and

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h. All disbursements of funds shall be subject to existing accounting and auditing rules and regulations.

D. 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, performance evaluation of program implementers, and fund management.

Operational details of the CHGS operations and Treatment Fund shall be incorporated in the MOA, Department Circulars, and/or Manual of Operations.

VII. REPEALING/ SEPARABILITY CLAUSE

AO No. 2014-0045, 2014-0045-A and other issuances that are inconsistent are hereby repealed/rescinded. If any provision of this Order is declared invalid, the other provisions not affected thereby shall remain valid and subsisting.

VIII. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication in a newspaper of general circulation.

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

Annex 9. NBS Milestones 1996 – 2020

February 22, 1996	First organizational meeting attended by representatives from different PPS and POGS accredited hospitals in Metro Manila
April 02, 1996	Creation of the NBS Study group composed of Pediatric and OB-Gynecology consultants from participating hospitals. Project name: Philippine Newborn Screening Project
June 27, 1996	Commencement of the Philippine Newborn Screening Project in 24 participating hospitals (18 private and 6 government)
June 1996 – September 1997	Coordination with the New South Wales Newborn Screening Program in Australia for test performance and analysis
September 18, 1997	Start of operation of the Newborn Screening Laboratory at the National Institutes of Health, UP Manila
March, 1999	Inclusion of the Newborn Screening Program in Child Health 2025, a planning framework on children's health of the Department of Health with the ultimate goal of achieving good health for all Filipino children by the year 2025
July 30, 1999	Creation of the Inter-agency Task Force on Newborn Screening composed of representatives from DOH as Chair, Institute of Human Genetics-National Institutes of Health, UP Manila, DILG, midwives' association, and other health groups
January 03, 2000	Issuance of Administrative Order # 1-A s 2000 by the Department of Health stating the Policies for the Nationwide Implementation of Newborn Screening (see Annex A)
July 19, 2000	Newborn Screening Study Group declared as Outstanding Health Research Awardee (OHRA) by the Philippine Council for Health Research and Development
February 07, 2001	Issuance of Department Order No. 29-C s 2001 by DOH, Subject: *"Creation of the National Technical Working Group on Newborn Screening Program under the National Center for Disease Prevention and Control"*. The group was tasked to provide direction and guidance for the nationwide implementation of the NBS program (see Annex B). DO 29-C s 2001 has been amended by DPO 2005-1660 to reconstitute the NTWG membership (see Annex C)

February 21, 2003	First National Awarding Ceremonies for the Outstanding Achievers in the Implementation of Newborn Screening sponsored by DOH and NIH
May 01, 2003	Canadian International Development Agency (CIDA) awards a financial grant to the Institute of Human Genetics to intensify promotional and advocacy work on newborn screening in Regions 4, 6, 10, with funds allocated for the writing of a Manual of Operations for newborn screening
December 09, 2003	Issuance of DOH Administrative Order No 121, s 2003, Subject: "*Strengthening Implementation of the National Newborn Screening System"* (see Annex D)
January 20, 2004	Issuance of the Presidential Proclamation No. 540, Subject: *"Declaring the First Week of October of each year as "National Newborn Screening Awareness Week"* (see Annex E)
April 07, 2004	Enactment of Republic Act 9288 known as the Newborn Screening Act of 2004 (see Annex F)
October 07, 2004	Signing of the Implementing Rules and Regulations of the Newborn Screening Act (see Annex G)
December 02, 2005	Opening of the 2nd Newborn Screening Center in Visayas at West Visayas State University Medical Center
January 22, 2006	Inclusion of NBS in the licensing requirement of Philippine hospitals; 90% of NBS fee covered by national health insurance [PhilHealth]
January 02, 2007	Opening of Scholarships for Genetics and Endocrinology Fellowship training for regions without specialists
December 2007	Inclusion of Newborn Screening in the PhilHealth's Newborn Care Package (NCP) (see Annex I)
June 12, 2008	Issuance of DOH Memo No. 2009 – 0123 imposing the following targets: 30% - 2008, 50% - 2009 and 85% by 2010 (see Annex J)
June 28, 2008	Creation of the NTWG Panel of Expert Committee
August 08, 2008	Issuance of AO No. 2008 – 0026 and 2008 - 0026A by DOH imposing penalties for non-implementation and/or overpricing of NBS (see Annex K)

May 20, 2009	Setting up of additional G6PD Confirmatory Centers (see Annex L)
July 7, 2009	Creation of the National Newborn Screening Follow-up Committee (NNSFC)
October 5, 2009	Opening of the 3rd Newborn Screening Center in Mindanao at the Southern Philippines Medical Center (formerly Davao Medical Center)
October, 2010	Opening of the 4th Newborn Screening Center at the Angeles University Foundation Medical Center Central Luzon
February, 2011	Creation of the Committee on Storage, Use and Disposal of the Residual Dried Blood Spots (DBS) (see Annex ___)
June, 2011	Initial offering of the MS Genetic Counseling Program by the Philippine General Hospital (PGH) – Department of Pediatrics and UP Manila College of Medicine
June 18, 2012	Started inclusion of Maple Syrup Urine Disease (MSUD) in the NBS Panel of Disorders
September, 2013	Opening of the 5th NSC in Region 4A (CALABARZON) at Daniel O. Mercado Medical Center in Tanauan City, Batangas
May 2, 2014	Setting up of Continuity Clinics in different parts of the Country
December 24, 2014	Expanded Newborn Screening – inclusion of more than 20+ disorders in the NBS Panel of Disorders
May, 2017	Opening of the 6th Newborn Screening Center in Northern Luzon at the Mariano Marcos Memorial Medical Center
October 4, 2018	Inclusion of Argininosuccinic Aciduria (ASA) in the NBS Panel of Disorders
January 5, 2019	Inclusion of the Expanded Newborn Screening in PhilHealth's Newborn Care Package
May 1, 2019	Full implementation of the Expanded Newborn Screening
October 27, 2020	Inclusion of Center for Human Genetics Services and details on the treatment and management in the Revised Guidelines on the Implementation of the Expanded Newborn Screening

Annex 10. Administrative Order No 2018 – 0025

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.

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).

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.

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 NSFs 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

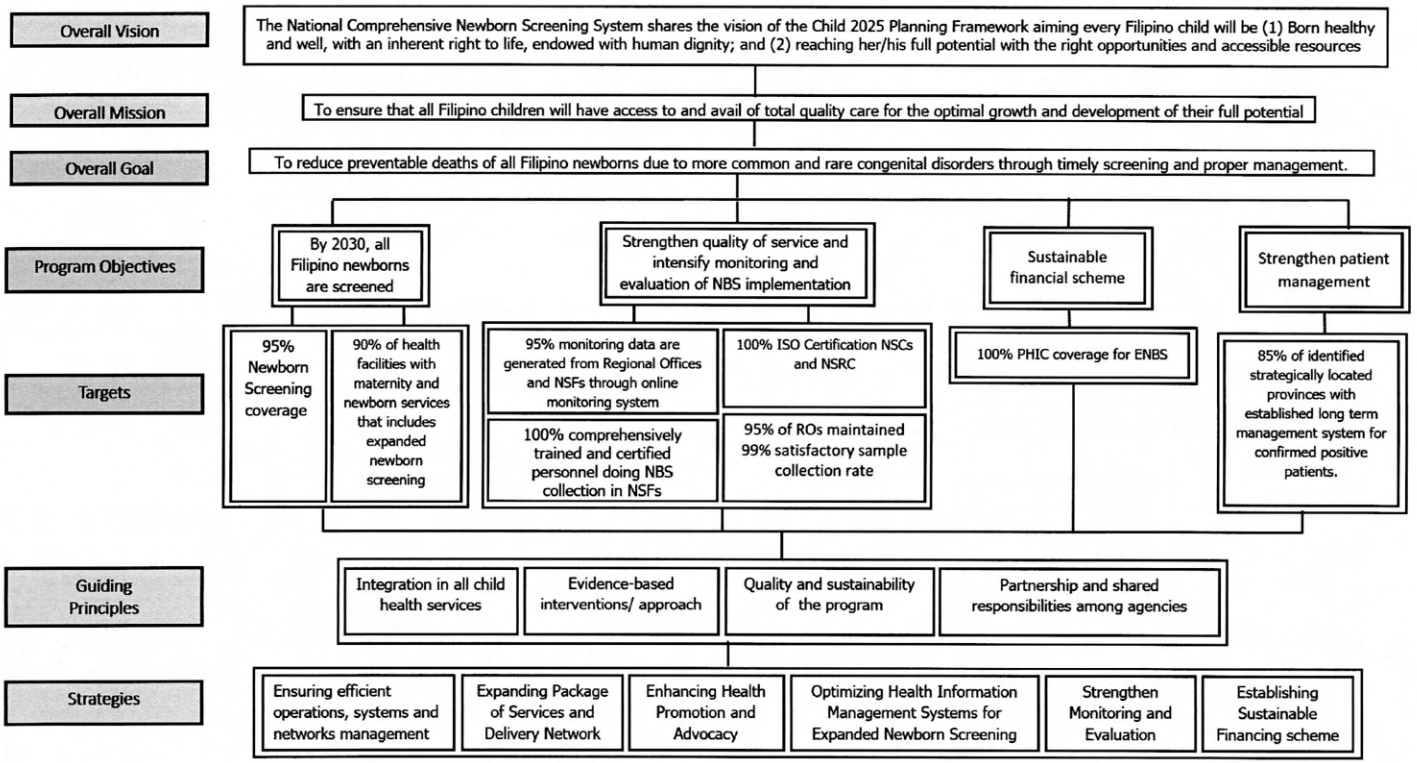
If any provision of this Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

IX. EFFECTIVITY

This Order shall take effect immediately.

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

Annex A: Strategic Framework



Page **1** of **6**

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

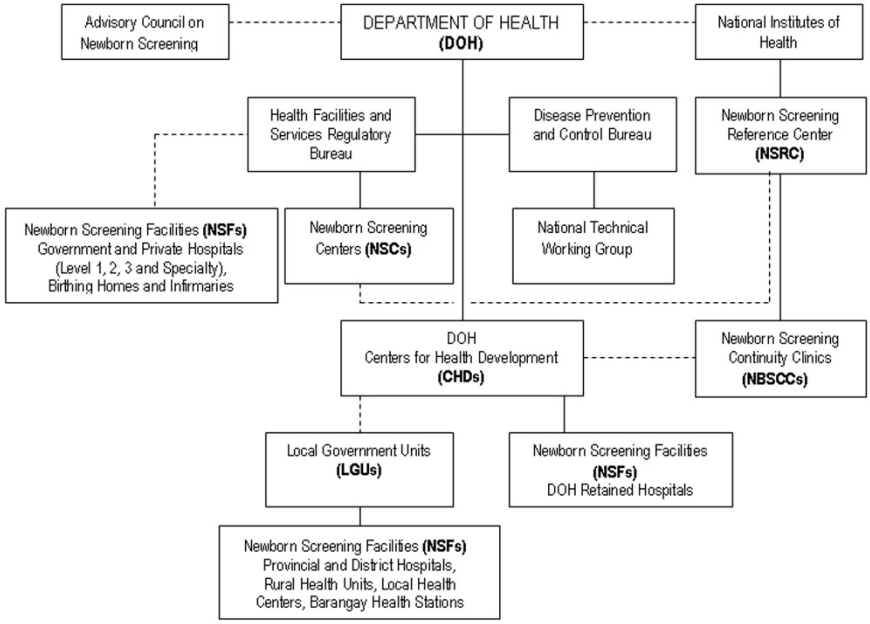
Annex D:

STRATEGIC PLAN FOR EXPANDED NEWBORN SCREENING GANTT CHART 2017-2030						
Strategies	**Major outcome/action points**	**Baseline 2017**	**2018-2020**	**2021-2023**	**2024-2026**	**2027-2030**
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.					

	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.					
	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.					

Annex 11. NCNBSS Functional Chart



Annex 12. Administrative Order 2016-0036 Revised Guidelines on the Utilization of the 4% Newborn Screening Fund by the DOH-CHDs and MOH BARMM

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 07 2016

ADMINISTRATIVE ORDER
No. 2016-0036

SUBJECT: **Revised Guidelines on the Utilization of the 4% Newborn Screening Fund by the Department of Health-Regional Offices and ARMM**

I. Rationale

To ensure the maximum and appropriate utilization of the Newborn Screening (NBS) 4% Fund by the Department of Health Regional Offices (DOH ROs) and DOH Autonomous Region in Muslim Mindanao (DOH-ARMM), the Advisory Committee on Newborn Screening (ACNBS) recommended the review of the NBS 4% Fund utilization and the subsequent release of Administrative Order 2013-0015 on April 16, 2013, which sets the guidelines on its utilization.

As provided in Section 16 of the Republic Act 9288, the said NBS 4% Fund shall be set aside from the NBS Fees for the DOH – Centers for Health Development (presently referred to as Regional Offices - ROs) or their future equivalent to be used solely for follow-up services, education and other activities directly related to the provision of newborn screening services. Such provision shall thereby contribute in ensuring the sustainability of the National Comprehensive Newborn Screening System (NCNBSS) and in subsequently reaching the vision of saving all Filipino newborns from mental retardation and death.

However, almost three years after the review of the fund utilization in 2012 and the release of the AO 2013-0015, gaps were still identified in the 4% Fund Utilization. Thus, during the meeting of the National Technical Working Group on Newborn Screening held on April 30, 2015, a thorough review of the fund utilization was recommended. The result of the review is embodied in the revision of AO 2013-0015 as outlined in this Administrative Order.

II. Objective

To expand the guidelines on the Newborn Screening 4% fund utilization of DOH-ROs and DOH-ARMM and to ensure appropriateness and maximized use for the NCNBSS.

III. Coverage

Provisions of this Administrative Order shall apply to all DOH-ROs, DOH-ARMM, Newborn Screening Reference Center (NSRC), Newborn Screening Centers (NSCs) and Newborn Screening Continuity Clinics.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 Local 1111, 1112, 1113, 1108
Direct Line (02) 711-9502; 9503 Fax: 743-1829; 743-1786 • URL: http://www.doh.gov.ph; e-mail: officeofsoh@doh.gov.ph

IV. Definition of Terms

a. *Newborn Screening* is an essential public health strategy to detect and manage congenital disorder to prevent mental retardation and death.

b. *RA 9288: Newborn Screening Act of 2004* refers to the act promulgating a comprehensive policy and a national system for ensuring newborn screening.

c. *Department of Health Central Office* is the lead agency in implementing the Republic Act 9288 or the Newborn Screening Act of 2004.

d. *Department of Health Regional Office* is the satellite offices of the Department of Health in every region, where each has a designated Newborn Screening (NBS) Coordinator as the key implementer of newborn screening program at the regional level.

e. *Newborn Screening Continuity Clinics* refers to an ambulatory clinic based in a tertiary hospital identified by the DOH to be part of the NCNBSS. It is equipped to facilitate continuity of care of confirmed patients in its area of coverage.

f. *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 (NIH), and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.

g. *Newborn Screening Reference Center (NSRC)* refers to the central facility at the National Institutes of Health (NIH) 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.

V. Policies and Procedures

a. General Guidelines

The earmarked amount to DOH-ROs/DOH-ARMM shall be for the purpose of implementing the newborn screening program and facilitating achievement of required outputs.

The 4% of the NBS Fee shall be set aside for the DOH ROs and DOH-ARMM to be used for follow-up services, education and other activities directly related to the provision of newborn screening services, incentive for RHU collecting health units, staff development of NBS personnel, capital outlay needed for NBS program implementation, and cost of repeat samples [Section 22, IRR of RA9288].

At least 30% of the total amount requested from the 4% NBS funds and transferred to each region shall be used for its Maintenance and Other Operating Expenses

(MOOE). Excluded from the said MOOE are the salaries and wages of NBS personnel.

B. Specific Guidelines

1. The 4% share of the DOH-ROs and DOH-ARMM shall be used for the following NBS-related activities:

   a) Follow-up service of patients with positive screening result by personnel hired for the NBS unit based at DOH-ROs/DOH-ARMM:

      The line item budget shall be used for the following:
      (1) Salaries and wages of Nurse and/or Medical Coordinator on contract of service and designated vehicle driver (if applicable);
      (2) Traveling expenses of monitoring visits;
      (3) Per diem of monitoring teams; and
      (4) Other related expenses.

   b) Follow-up service of patients confirmed positive by personnel hired for the NBS unit based at Newborn Screening Continuity Clinics.

      The line item budget shall be used for the following:
      (1) Salaries and wages of Nurse/Genetic Counselor and/or Medical Coordinator on contract of service;
      (2) Traveling expenses of monitoring visits/attendance to trainings/conferences;
      (3) Per diem of monitoring team;
      (4) Indigency funds for laboratory tests and long-term management; and
      (5) Other related expenses.

   c) Education and other activities directly related to the provision of NBS services.

      The line item budget shall be used for the following:

      (1) Meetings with municipal/provincial/Newborn Screening Facility Coordinators;
      (2) Venue and food of participants during the conduct of lectures/trainings/orientation seminars;
      (3) Supplies and materials needed for the conduct of lectures/trainings/orientation seminars;
      (4) Honoraria of resource persons/facilitators;
      (5) Traveling expenses and per diem for the conduct of training/orientation seminars;
      (6) Printing and reproduction of advocacy and information materials; and

(7) Other training/seminar and campaign related expenses.

d) Incentives for RHU collecting health units of AT LEAST 2% of the 4% funds of the DOH-ROs/DOH-ARMM.

Incentive may be in the form of;
(1) NBS kits;
(2) Sponsorship to newborn screening – related local meetings and conferences;
(3) Promotional materials/giveaways; or
(4) Telecommunication expenses related to newborn screening activities.

e) Staff development of the personnel of the NBS unit based at the DOH-ROs/DOH-ARMM and Continuity Clinics.

The line item budget shall be used for the following:
(1) Registration fees of trainings/seminars/conventions/ official meetings;
(2) Traveling and accommodation expenses;
(3) Per diem of staff directly involved in the program; and
(4) Attendance to international conferences approved by DOH-Screening & Evaluation Committee for Training & Development (SECTD). Approval shall be based on the following:

(a) An official country representative involving a highly specialized field that is related in the program management or policy development; and
(b) The conference focus on newborn screening program management and policy development; and
(c) Paper or poster presenter/s on newborn screening-related services/innovation; or
(d) Oral presenter/invited resource person representing the country either in plenary or in parallel session.

Post travel report shall be submitted two weeks after travel.

f) Capital outlay

The line item budget shall be used for the following:
(1) Purchase of Office Equipment, Communication Equipment, IT Equipment and Software, Furniture and Fixtures needed in the implementation of the NBS program;
(2) Purchase of Motor Vehicle for NBS program, which shall abide by the following rules:

(a) Each RO can acquire one (1) vehicle subject to government procurement process. Request for a

second vehicle shall require approval of the Advisory Committee on Newborn Screening (ACNBS);

(b) The type of vehicle is limited to SUVs/4-wheel drive or its equivalent. The vehicle will have a vehicle wrap using a prescribed DOH-NBS standard design approved by the DOH;

(c) The motor vehicle shall be for official use only and shall be primarily for monitoring and evaluation of the implementation of NBS program at health facilities, government and private, at all levels, patient recall, advocacy, technical and logistics assistance to Local Government Units (LGUs), Non–governmental organizations (NGOs), Academic Institutions and other stakeholders; monitoring and supervision activities on NBS facilities; for other functions officially related to the implementation of the NBS Program;

(d) The vehicle shall be for official NBS use only; and

(e) The designation of driver will be dependent on the set up of each region with the objective of ensuring proper usage and maintenance of their vehicle.

g) Maintenance and operating expenses of the program

The line item budget shall be used for the following:

(1) Telephone bills/Call Cards (Landline and mobile phones);
(2) Office Supplies and Other Supplies Expenses;
(3) Internet Expenses;
(4) Representation Expenses;
(5) Repairs and Maintenance of acquired Properties & Equipment; and
(6) Other Administrative Overhead related expenses.

h) Cost of repeat samples due to insufficient and contaminated samples of patients in their catchment area.

2. NBS Nurse Coordinators shall be in-charge of the monitoring of funds transferred to DOH-ROs/DOH-ARMM.

3. All disbursement of funds shall be subject to existing accounting and auditing rules and regulations.

4. These guidelines shall be reviewed periodically by the Family Health Office of the Department of Health (FHO-DOH) for technical processes and Newborn Screening Reference Center for the usage of fund.

C. Roles and Responsibilities

1. DOH ROs/DOH-ARMM shall:

a) Maintain a Trust Fund account for the 4% earmarked amount;
b) Take charge of the overall management and disbursement of the transferred fund;
c) Submit the following approved documents, namely: (1) Internal Operating Budget (IOB) for the calendar year, (2) Work and Financial Plan (WFP), (3) Accomplishment report, and (4) any supplemental plans to DOH-Disease and Prevention Control Bureau.
d) Prepare and submit to NSRC the request letter for fund transfer along with the original copy of approved documents, namely: (1) Fund utilization report (FUR) verified by Resident COA; (2) Internal Operating Budget (IOB) for the calendar year; (3) Work and Financial Plan (WFP); (4) Accomplishment report and (5) supplemental plans (if any); and
e) Utilize the unexpended balance of the 4% funds from the previous year/s for the NBS activities of the following year.

2. NSRC shall:

a) Review fund transfer request based on the approved and submitted FUR, IOB, WFP and Accomplishment Report. Findings shall be elevated to the DOH-FHO;
b) Request funding and payment approval from UP Manila of the funds for transfer to DOH-ROs/DOH-ARMM; and
c) Transfer earmarked funds to DOH-ROs and DOH-ARMM within 45 working days from date of receipt of requests.

D. Procedural Guidelines

1. A Memorandum of Agreement (MOA) shall be executed between NSRC, NSCs and DOH-ROs/DOH-ARMM on the collection and transfer of 4% of NBS fees;
2. NSRC shall collect from NSCs the percentage of the NBS fees for DOH-ROs/DOH-ARMM;
3. NSRC shall notify the DOH-ROs/DOH-ARMM on the availability of 4% of NBS fees;
4. DOH-ROs/DOH-ARMM shall request from NSRC the amount for transfer as indicated in the DOH-ROs/DOH-ARMM Annual Internal Operating Budget (IOB);
5. NSRC shall transfer earmarked funds to the DOH-ROS/DOH-ARMM; and
6. DOH Central office shall facilitate monitoring and evaluation of fund utilization of and fund requests from DOH-ROs/DOH-ARMM, in coordination with NSRC. Assessment shall be reported and resolutions to critical issues shall be discussed by the DOH Central Office with the region/s concerned.

VI. Repealing Clause

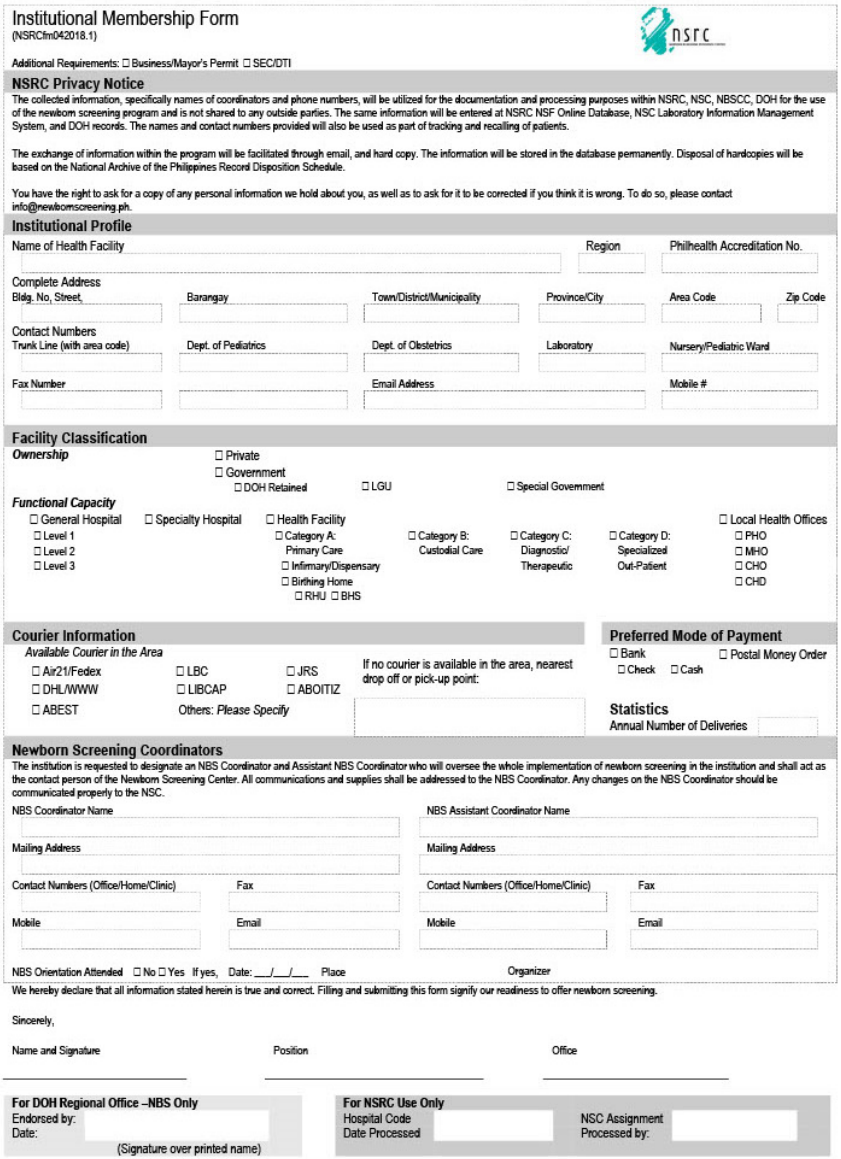
AO No. 2013-0015 and all other Orders whose provisions are inconsistent with this Order are hereby repealed/modified.

VI. Effectivity

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

PAULYN JEAN B. ROSELL-UBIAL, MD.,MPH, CESO II
Secretary of Health

Annex 13. Institutional Database Form



Institutional Membership Form
(NSRCfm042018.1)

nsrc

Additional Requirements: ☐ Business/Mayor's Permit ☐ SEC/DTI

NSRC Privacy Notice

The collected information, specifically names of coordinators and phone numbers, will be utilized for the documentation and processing purposes within NSRC, NSC, NBSCC, DOH for the use of the newborn screening program and is not shared to any outside parties. The same information will be entered at NSRC NSF Online Database, NSC Laboratory Information Management System, and DOH records. The names and contact numbers provided will also be used as part of tracking and recalling of patients.

The exchange of information within the program will be facilitated through email, and hard copy. The information will be stored in the database permanently. Disposal of hardcopies will be based on the National Archive of the Philippines Record Disposition Schedule.

You have the right to ask for a copy of any personal information we hold about you, as well as to ask for it to be corrected if you think it is wrong. To do so, please contact info@newbornscreening.ph.

Institutional Profile

Name of Health Facility | Region | Philhealth Accreditation No.

Complete Address
Bldg. No, Street, | Barangay | Town/District/Municipality | Province/City | Area Code | Zip Code

Contact Numbers
Trunk Line (with area code) | Dept. of Pediatrics | Dept. of Obstetrics | Laboratory | Nursery/Pediatric Ward

Fax Number | Email Address | Mobile #

Facility Classification

Ownership
☐ Private
☐ Government
☐ DOH Retained ☐ LGU ☐ Special Government

Functional Capacity
☐ General Hospital ☐ Specialty Hospital ☐ Health Facility ☐ Local Health Offices
☐ Level 1 ☐ Level 2 ☐ Level 3
☐ Category A: Primary Care ☐ Infirmary/Dispensary ☐ Birthing Home ☐ RHU ☐ BHS
☐ Category B: Custodial Care
☐ Category C: Diagnostic/ Therapeutic
☐ Category D: Specialized Out-Patient
☐ PHO ☐ MHO ☐ CHO ☐ CHD

Courier Information

Available Courier in the Area
☐ Air21/Fedex ☐ LBC ☐ JRS
☐ DHL/WWW ☐ LIBCAP ☐ ABOITIZ
☐ ABEST Others: *Please Specify*

If no courier is available in the area, nearest drop off or pick-up point:

Preferred Mode of Payment
☐ Bank ☐ Postal Money Order
☐ Check ☐ Cash

Statistics
Annual Number of Deliveries

Newborn Screening Coordinators

The institution is requested to designate an NBS Coordinator and Assistant NBS Coordinator who will oversee the whole implementation of newborn screening in the institution and shall act as the contact person of the Newborn Screening Center. All communications and supplies shall be addressed to the NBS Coordinator. Any changes on the NBS Coordinator should be communicated properly to the NSC.

NBS Coordinator Name | NBS Assistant Coordinator Name
Mailing Address | Mailing Address
Contact Numbers (Office/Home/Clinic) | Fax | Contact Numbers (Office/Home/Clinic) | Fax
Mobile | Email | Mobile | Email

NBS Orientation Attended ☐ No ☐ Yes If yes, Date: ___/___/___ Place Organizer

We hereby declare that all information stated herein is true and correct. Filling and submitting this form signify our readiness to offer newborn screening.

Sincerely,

Name and Signature | Position | Office

For DOH Regional Office –NBS Only
Endorsed by:
Date:
(Signature over printed name)

For NSRC Use Only
Hospital Code
Date Processed
NSC Assignment
Processed by:

Annex 14: Pink Brochure / FAQs About Newborn Screening

HELP US SAVE BABIES AFFECTED BY ANY OF THESE DISORDERS.

Endocrine Disorders
- Congenital Hypothyroidism
- Congenital Adrenal Hyperplasia

Amino Acid Disorders
- Homocystinuria
- Hypermethioninemia/Methionine Adenosine Transferase Deficiency
- Maple Syrup Urine Disease
- Phenylketonuria
- Tyrosinemia Type I
- Tyrosinemia Type II, III

Fatty Acid Disorders
- Carnitine Palmitoyltransferase I Deficiency
- Carnitine Palmitoyltransferase II Deficiency
- Carnitine Uptake Deficiency
- Glutaric Acidemia Type II
- Long Chain Hydroxyacyl-CoA Dehydrogenase Deficiency
- Medium Chain-Acyl-CoA Dehydrogenase Deficiency
- Very Long Chain-Acyl-CoA Dehydrogenase Deficiency
- Tri-functional Protein Deficiency

Organic Acid Disorders
- 3-Methylcrotnyl CoA Carboxylase Deficiency
- Beta Ketothiolase Deficiency
- Glutaric Acidemia Type I
- Isovaleric Acidemia
- Methylmalonic Acidemia
- Multiple Carboxylase Deficiency
- Propionic Acidemia

Urea Cycle Defect
- Citrullinemia
- Argininosuccinic Aciduria

Hemoglobinopathies
- Alpha Thalassemia
- Beta Thalassemia
- Hemoglobin C
- Hemoglobin D
- Hemoglobin E
- Sickle Cell Disease

Others
- Galactosemia
- Glucose-6-Phosphate Dehydrogenase Deficiency
- Cystic Fibrosis
- Biotinidase Deficiency

REMINDERS TO PARENTS

G6PD deficiency is the most common condition among the ENBS Panel of Disorders.

Napthalene or moth ball, and some drugs including herbal medicine should be avoided by people with G6PD deficiency.

While waiting for the ENBS result, parents are advised not to expose their baby to moth ball. More so, all medications that will be given to the baby must be prescribed by a doctor.

If the ENBS result is G6PD deficient, consult the baby's doctor and proceed with the confirmatory test. Refer the result to your physician.

For further inquiries, please contact:

Your health workers at the hospitals / lying-in clinics / birthing homes / health centers

Newborn Screening Center - Northern Luzon
Mariano Marcos Memorial Hospital and Medical Center
San Julian, City of Batac, Ilocos Norte

Newborn Screening Center - Central Luzon Angeles
University Foundation Medical Center
MacArthur Highway, Brgy. Salapungan, Angeles City

Newborn Screening Center - National Institutes of Health
Building H, UP Ayala Land Technohub Complex
Brgy. UP Campus, Commonwealth Ave., Diliman, Quezon City

Newborn Screening Center - Southern Luzon
Daniel O Mercado Medical Center
143 Narra St., Mountview Subd., Tanauan City

Newborn Screening Center - Visayas
West Visayas State University Medical Center
E. Lopez St., Jaro, Iloilo City

Newborn Screening Center - Mindanao
Southern Philippines Medical Center
J.P. Laurel Ave., Bajada, Davao City

Newborn Screening Reference Center
National Institutes of Health, UP Manila
1579 F. T. Benitez St., Ermita, Manila

E-mail: info@newbornscreening.ph
URL: www.newbornscreening.ph

SAVE YOUR BABY
FROM MENTAL RETARDATION

PhilHealth
Your Partner in Health

Basic Information About Expanded Newborn Screening

What is newborn screening?
Newborn Screening (NBS) is a simple procedure to find out if your baby has a congenital disorder that may lead to mental retardation or even death if left untreated.

What is Expanded Newborn Screening (ENBS)?
The expanded newborn screening program increased the screening panel of disorders from six (6) to more than twenty-eight.

Why is it important?
Most babies with metabolic disorders look "normal" at birth. By doing ENBS, metabolic disorders may be detected even before clinical signs and symptoms are present. As a result of this, treatment can be given early to prevent consequences of untreated conditions.*

When is it done?
ENBS is ideally done immediately after 24 hours from birth.

How is it done?
A few drops of blood are taken from the baby's heel, blotted on a special absorbent filter card and then sent to Newborn Screening Center (NSC).

Who will collect the sample for ENBS?
The blood sample for ENBS may be collected by any of the following: physician, nurse, medical technologist or trained midwife.

Where is ENBS available?
ENBS is available in hospitals, lying-ins, rural health units, health centers and some private clinics.

How much is ENBS?
Expanded newborn screening costs ₱1750 and is included in the Newborn Care Package (NCP) for PhilHealth members.

What is Newborn Care Package?
NCP is a PhilHealth benefit package for essential health services of the newborn during the first few days of life. It covers essential newborn care, expanded newborn screening, and hearing screening tests.

What are the eligibility conditions for newborn to avail of the NCP?
Newborns are eligible for NCP if **all** of the following are met:
- Either of the parents are eligible to avail of the benefits,
- Born in accredited facilities that perform deliveries, such as hospitals and birthing homes; and
- Services were availed of upon delivery.

How can results be claimed?
Results can be claimed from the health facility where ENBS was availed. Normal ENBS results are available by 7 - 14 working days from the time samples are received at the NSC.

Positive ENBS results are relayed to the parents immediately by the health facility. Please ensure that the address and phone number you will provide to the health facility are correct.

What is the meaning of the newborn screening result?

A NEGATIVE SCREEN means that the ENBS result is normal.

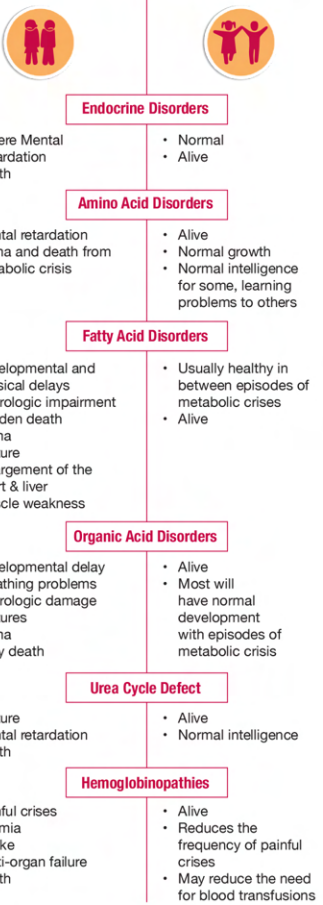
A POSITIVE SCREEN means that the newborn must be brought back to his/her health practitioner for further testing.

What must be done when a baby has a positive ENBS result?
Babies with positive results must be referred at once to a specialist for confirmatory testing and further management.

What happens to the dried blood samples after screening?
After the dried blood spot has been tested, it will be stored in a secure locked area. The stored sample is retained to allow for normal quality assurance and may be used for ethics committee approved researches for the benefit of the general public.

**Long term follow-up and management of children with confirmed newborn screening conditions ensure that these children receive the full benefits of early identification through newborn screening.*

WHY SCREEN YOUR BABIES?



Expanded Newborn Screening Pink Brochure (Filipino)

PAGTULUNGAN NATING ILIGTAS ANG SANGGOL NA MAAARING MAAPEKTUHAN NG MGA SAKIT NA ITO.

Endocrine Disorders
- Congenital Hypothyroidism
- Congenital Adrenal Hyperplasia

Amino Acid Disorders
- Homocystinuria
- Hypermethioninemia/Methionine Adenosine Transferase Deficiency
- Maple Syrup Urine Disease
- Phenylketonuria
- Tyrosinemia Type I
- Tyrosinemia Type II, III

Fatty Acid Disorders
- Carnitine Palmitoyltransferase I Deficiency
- Carnitine Palmitoyltransferase II Deficiency
- Carnitine Uptake Deficiency
- Glutaric Acidemia Type II
- Long Chain Hydroxyacyl-CoA Dehydrogenase Deficiency
- Medium Chain-Acyl-CoA Dehydrogenase Deficiency
- Very Long Chain-Acyl-CoA Dehydrogenase Deficiency
- Tri-functional Protein Deficiency

Organic Acid Disorders
- 3-Methylcrotnyl CoA Carboxylase Deficiency
- Beta Ketothiolase Deficiency
- Glutaric Acidemia Type I
- Isovaleric Acidemia
- Methylmalonic Acidemia
- Multiple Carboxylase Deficiency
- Propionic Acidemia

Urea Cycle Defect
- Citrullinemia
- Argininosuccinic Aciduria

Hemoglobinopathies
- Alpha Thalassemia
- Beta Thalassemia
- Hemoglobin C
- Hemoglobin D
- Hemoglobin E
- Sickle Cell Disease

Others
- Galactosemia
- Glucose-6-Phosphate Dehydrogenase Deficiency
- Cystic Fibrosis
- Biotinidase Deficiency

PAALALA SA MGA MAGULANG

Ang kakulangan sa G6PD ay ang pinaka-karaniwang uri ng kondisyon na kasama sa ENBS.

Ang naptalina o moth ball, ilang gamot kabilang ang halamang gamot ay bawal sa mga taong may kakulangan sa G6PD.

Habang hinihintay ang resulta ng ENBS, pinapaalala sa mga magulang na iwasang ilantad ang kanilang mga anak sa naptalina. Lahat ng gamot na ibibigay sa bata ay dapat may reseta ng doktor.

Kung ang resulta ng ENBS ay may kakulangan sa G6PD, kumunsulta sa doktor at magpa-confirmatory test upang malaman kung talagang kulang sa G6PD ang bata. Ipakita ang resulta ng confirmatory test sa inyong doktor.**

Para sa karagdagang katanungan, makipag-ugnayan:

sa health workers ng ospital o lying-in clinics / birthing homes o health centers

Newborn Screening Center - Northern Luzon
Mariano Marcos Memorial Hospital and Medical Center
San Julian, City of Batac, Ilocos Norte

Newborn Screening Center - Central Luzon
Angeles University Foundation Medical Center
MacArthur Highway, Brgy. Salapungan, Angeles City

Newborn Screening Center - National Institutes of Health
Building H, UP Ayala Land Technohub Complex
Brgy. UP Campus, Commonwealth Ave., Diliman, Quezon City

Newborn Screening Center - Southern Luzon
Daniel O Mercado Medical Center
143 Narra St., Mountview Subd., Tanauan City

Newborn Screening Center - Visayas
West Visayas State University Medical Center
E. Lopez St., Jaro, Iloilo City

Newborn Screening Center - Mindanao
Southern Philippines Medical Center
J.P. Laurel Ave., Bajada, Davao City

Newborn Screening Reference Center
National Institutes of Health, UP Manila
1579 F. T. Benitez St., Ermita, Manila

E-mail: info@newbornscreening.ph
URL: www.newbornscreening.ph

ILIGTAS ANG INYONG ANAK
SA MENTAL RETARDATION

PhilHealth

Isinalin sa Filipino ng
SENTRO NG WIKANG FILIPINO
Unibersidad ng Pilipinas - Manila

Mga dapat malaman tungkol sa Expanded Newborn Screening

Ano ang Newborn Screening?
Ang newborn screening (NBS) ay isang simpleng pamamaraan upang malaman kung ang sanggol ay may congenital disorder na maaring maging sanhi ng mental retardation o maagang pagkamatay.

Ano ang Expanded Newborn Screening (ENBS)?
Ang ENBS ay pinalawak na programa ng newborn screening na makapagsusuri ng mas maraming sakit mula anim (6) hanggang sa mahigit 28.

Bakit mahalaga ang ENBS?
Karamihan sa mga sanggol na may congenital disorders ay mukhang normal pagkapanganak. Sa pamamagitan ng ENBS, ang mga kondisyong ito ay maaaring malaman na bago pa lumabas ang mga sintomas. Dahil dito, mabibigyan kaagad ng karampatang lunas upang maiwasan ang mental retardation o maagang pagkamatay.*

Kailan at saan ginagawa ang ENBS?
Ang ENBS ay dapat na gawin makalipas ang 24 oras pagkapanganak sa mga ospital, lying-in o paanakan, health centers, at pribadong klinik na sertipikado ng DOH at NIH.

Paano ginagawa ang ENBS?
Kumukuha ng ilang patak ng dugo mula sa sakong ng sanggol, inilalagay sa isang espesyal na papel (filter card), at ipinapadala sa Newborn Screening Center (NSC). May mga impormasyon na hihingin ang ospital/lying- in/health center tulad ng tirahan at telepono. Siguraduhing tama ang mga ito. Maglalabas ng resulta ng ENBS matapos ang 7-14 working days pagkatanggap ng NSC.

Sino ang maaaring kumuha ng dugo para sa ENBS?
Ang ENBS ay maaaring gawin ng mga sumusunod: doktor, nars, medical technologist, o nagsanay na midwife.

Magkano ang ENBS?
Nagkakahalaga ng P1,750 ang ENBS at kasama ito sa PhilHealth Newborn Care Package, benepisyong pangkalusugan para mga sanggol sa mga unang araw pagkapanganak.

Paano makukuha ang resulta ng ENBS?
Kunin ang resulta sa ospital, lying-in o paanakan, health centers, o pribadong klinik kung saan ito isinagawa.

Negatibong resulta (NEGATIVE)
- nangangahulugan na NORMAL ang test

Positibong resulta (POSITIVE)
- nangangahulugan na dapat dalhin kaagad ang sanggol sa doktor para sa karagdagang pagsusuri. Ito ay agad na ipinapapaalam sa mga magulang. Sasabihan kayo ng doktor kung kailangang ulitin ang test kaagad o ipakonsulta sa pinakamalapit na ospital o espesyalista ang inyong anak para sa confirmatory test** at sa iba pang dapat gawin.

Ano ang mangyayari sa dried blood spot matapos ang screening?
Matapos dumaan sa pagsusuri, ang dried blood spot ay mananatili sa isang ligtas na lugar. Ito ay itatago at maaring gamitin para sa pananaliksik na binigyang-pahintulot ng lupon ng etika para sa kapakinabangan ng nakararami.

**Ang maagang kaalaman tungkol sa ENBS ay mahalaga upang makatanggap ng pangmatagalang pamamahalang pangkalusugan ang mga batang may kumpirmadong kondisyon na sinusuri sa ENBS.*
***Ang confirmatory test ay karagdagang pagsusuri upang matiyak ang kondisyon na nakita sa ENBS.*

BAKIT KAILANGANG MALAMAN NANG MAS MAAGA ANG KAHALAGAHAN NG ENBS?

Maaring Kahinatnan pag HINDI na ENBS	Maaring Kahinatnan pag na-ENBS at nagamot kaagad*
Endocrine Disorders	
• Malubhang Mental Retardation • Kamatayan	• Normal • Buhay
Amino Acid Disorders	
• Mental retardation • Coma at kamatayan mula sa metabolic crisis	• Buhay • Normal na paglaki • Normal na katalinuhan sa iba, problema sa pagkatuto para sa iba
Fatty Acid Disorders	
• Pagkaantalang developmental at pisikal • Neurologic impairment • Biglaang kamatayan • Coma • Kumbulsiyon • Paglaki ng puso at atay • Mahinang kalamnan	• Malusog sa pagitan ng mga kabanata ng metabolic crisis • Buhay
Organic Acid Disorders	
• Pagkaantalang developmental • Hirap sa paghinga • Neurologic damage • Kumbulsiyon • Coma • Maagang pagkamatay	• Buhay • Karamihan ay may normal na paglaki ngunit may kabanata ng metabolic crisis
Urea Cycle Defect	
• Kumbulsiyon • Mental retardation • Kamatayan	• Buhay • Normal na katalinuhan
Hemoglobinopathies	
• Painful crisis • Anemia • Stroke • Multi-organ failure • Kamatayan	• Buhay • Bihirang painful crisis • Bumababa ang pangangailangan na salinan ng dugo

Annex 15. NBS Refusal Form

English

National Comprehensive Newborn Screening System

REFUSAL FORM

Date: _____

Newborn Screening Facility:_____

Republic Act 9288 also known as the "***Newborn Screening Act of 2004***" provides for a comprehensive national policy to ensure that every newborn in the Philippines has access to newborn screening services that can detect heritable metabolic conditions that can result in ***mental retardation***, ***serious health complications*** and ***death***.

The health practitioners in this health facility have informed the undersigned of newborn screening, its procedure, its benefits, its availability in this facility and the catastrophic consequences of undiagnosed metabolic conditions. As parent/guardian of _____, I refuse to have newborn screening done for the
(Name of Patient/Newborn)

following reasons: _____
(Please indicate reason/s) _____
_____
_____

I declare with full knowledge and competence that this institution and the health workers therein shall be free from all liabilities under the law because this refusal for newborn screening is of my decision.

I understand that a copy of this refusal form shall be part of the permanent medical records of my child/ward and will be part of a national registry/database of the National Comprehensive Newborn Screening System.

Witness/es:

_____ _____
Signature over Printed Name of Parent/Guardian

Signature over Printed Name/Designation

Filipino

National Comprehensive Newborn Screening System

KASULATAN NG PAGTANGGI

Petsa: _____

Newborn Screening Facility: _____

Nakasaad sa batas ng Newborn Screening Act of 2004 (Republic Act 9288) na ang bawat bagong panganak sa Pilipinas ay tiyak na may akses sa serbisyong 'newborn screening'. Ang 'newborn screening' ay isang paraan ng maagang pagtuklas ng ilang metabolic condition na maaaring maging sanhi ng mental retardation, malalang kumplikasyon sa kalusugan at maagang kamatayan.

Ipinaliwanag sa akin ng pasilidad ang mga sumusunod:

- ☑ Ang pamamaraan ng newborn screening
- ☑ Ang pasilidad ay nag-aalok ng newborn screening
- ☑ Ang magandang epekto ng pagpapa-newborn screening
- ☑ Ang masamang epekto ng di pagpapa-newborn screening ng bagong panganak na sanggol

Sa kabila nito, tumatanggi pa rin ako, bilang magulang/tagapangalaga na ipa-newborn screening ang sanggol/anak na si _____ sa mga
(Pangalan ng Sanggol)
sumusunod na kadahilanan _____
_____
(Dahilan ng Pagtanggi)

Sa aking sapat na kaalaman at kakayahan, walang pananagutan sa batas ang institusyong ito, _____ at ang mga nagtatrabaho dito sa aking desisyong pagtangging ipa-newborn screening ang sanggol.

Naunawaan kong ang kopya ng kasulatan ng pagtangging ito ay magiging parte ng permanenteng rekord ng aking anak/bata sa aking pangangalaga at magiging bahagi din ng database ng *National Comprehensive Newborn Screening System*.

Mga Testigo:

_____
Pirma sa ibabaw ng Pangalan
ng Magulang/Tagapangalaga

_____
Pirma sa ibabaw ng
Pangalan/Designasyon

Annex 16. Simple Spot Check Poster

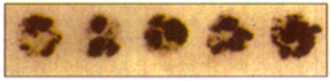
Simple Spot Check

Valid Specimen

Allow a sufficient quantity of blood to soak through to completely fill the pre-printed circle on the filter paper. Fill all required circles with blood. Do not layer successive drops of blood or apply blood more than once in the same collection circle. Avoid touching or smearing spots.

Invalid Specimens:

Possible Causes:



1. Specimen quantity insufficient for testing.

- Removing filter paper before blood has completely filled circle or before blood has soaked through to second side.
- Applying blood to filter paper with a capillary tube.
- Touching filter paper before or after blood specimen collection with gloved or ungloved hands, hand lotion, etc.
- Allowing filter paper to come in contact with gloved or ungloved hands or substances such as hand lotion or powder, either before or after blood specimen collection.

2. Specimen appears scratched or abraded.

- Applying blood with a capillary tube or other device.

3. Specimen not dry before mailing.

- Mailing specimen before drying for a minimum of four hours.

4. Specimen appears supersaturated.

- Applying excess blood to filter paper, usually with a device.
- Applying blood to both sides of filter paper.

5. Specimen appears diluted, discolored or contaminated.

- Squeezing or "milking" of area surrounding the puncture site.
- Allowing filter paper to come in contact with gloved or ungloved hands or substances such as alcohol, formula, antiseptic solutions, water, hand lotion or powder, etc., either before or after blood specimen collection.
- Exposing blood spots to direct heat.

6. Specimen exhibits serum rings.

- Not wiping alcohol from puncture site before making skin puncture.
- Allowing filter paper to come in contact with alcohol, hand lotion, etc.
- Squeezing area surrounding puncture site excessively.
- Drying specimen improperly.
- Applying blood to filter paper with a capillary tube.

7. Specimen appears clotted or layered.

- Touching the same circle on filter paper to blood drop several times.
- Filling circle on both sides of filter paper.

8. No blood.

- Failure to obtain blood specimen.

Not for Sale

Annex 17. Transmittal Form

Newborn Screening Center - NIH
Institute of Human Genetics, University of the Philippines Manila
Rm 102, Building H, UP Ayala Land TechnoHub Complex
Commonwealth Avenue, Diliman, Quezon City, 1101 Philippines
Tel. Nos. (632) 3760962•3760964•3760965•3760967
Fax No. (632) 9216395
email: nsc-nih@up.edu.ph

TRANSMITTAL FORM

Name of Hospital: _____

Hospital Code : _____

With this package are the following:

OF INITIAL SAMPLES : _____
OF REPEAT SAMPLES : _____
TOTAL : _____

INITIAL SAMPLES:

Mother's name (Last Name, First Name)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____
17. _____
18. _____
19. _____
20. _____
21. _____
22. _____
23. _____
24. _____
25. _____

REPEAT SAMPLES:

Mother's name (Last Name, First Name)

1. _____
2. _____
3. _____
4. _____
5. _____

PAYMENTS:

Landbank Deposit Slip: _____
Check : _____
Others : _____

REMARKS: _____

_____

Prepared by : _____
(*Signature over printed name*)
Date prepared : _____
Verified by : _____
(*Signature over printed name*)

**Preparation and verification of package should be done by two different persons.*

NBS-FO-02, Rev.01

Annex 18. NBS Results (Within Normal Limits)

Individual Result Parent's Copy (Within Normal Limits)

Newborn Screening Center
Address 1
Address 2
Contact Details

Report run date: January 29, 2021

SAMPLE ID:	20210290003	**DATE OF BIRTH:**	1/25/2021
MOTHER'S NAME:	XXXXX XXXX	**DATE OF COLLECTION:**	1/26/2021
MULTIPLE:	0	**DATE RECEIVED:**	1/29/2021
SEX:	MALE	**AGE AT COLLECTION:**	1 day/s and 3 hour/s
FEEDING TYPE:	Breast	**BIRTHWEIGHT:**	2,892 gms
		AGE OF GESTATION:	38 weeks

HOSPITAL/PLACE OF COLLECTION:
XXX XXXXXXXXX XXXX
XXX XXXXXXXXX XXXX

ADDRESS TO NBS COORDINATOR
XX XXXXXX XXXXX
ATTENTION TO HEALTH PRACTITIONER
XXXXXX

NEWBORN SCREENING RESULTS

DISORDERS	REMARKS
Congenital Hypothyroidism (CH)	Within Normal Limits
Congenital Adrenal Hyperplasia (CAH)	Within Normal Limits
Galactosemia (TG)	Within Normal Limits
Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD)	Within Normal Limits
Amino Acid Disorders (AA)	Within Normal Limits
Organic Acid Disorders (OA)	Within Normal Limits
Fatty Acid Disorders (FAO)	Within Normal Limits
Biotinidase Deficiency (BTND)	Within Normal Limits
Cystic Fibrosis (CF)	Within Normal Limits
Urea Cycle Disorders (UC)	Within Normal Limits
Hemoglobinopathies (HGB)	Within Normal Limits

INSTRUCTIONS:

Within Normal Limits
Normal result for the screened disorder.

XXXXXXXXXXXXXX
Laboratory Manager

XXXXXXXXXXXXXX
Unit Head

This is a computer-generated report. Signature is not required.

Summary Report to NSF (Within Normal Limits)

Newborn Screening Center
Address 1
Address 2
Contact Details

Report run date: January 29, 2021

ATTENTION:

Name of Hospital of Collection:
XXXX XXXXXX XXXXXXXXX
Address of Hospital:
XXXX XXXXXX XXXX

Name of NBS Coordinator:
XXXX XXXXXX XXXXXXX

The following patients were found to be NORMAL for all screened disorders.

Sample ID	Mother's Name	Multiple	Date of Birth	Sex	Date Received	Date Collected	Physician
20210220191	XXXXXXX XXXXX	0	01/15/2021	FEMALE	1/22/2021	01/16/2021	XXXXX
20210220192	XXXXXXX XXXXX	0	01/15/2021	FEMALE	1/22/2021	01/16/2021	XXXXX
20210220193	XXXXXXX XXXXX	0	01/15/2021	FEMALE	1/22/2021	01/16/2021	XXXXX
20210220194	XXXXXXX XXXXX	0	01/16/2021	FEMALE	1/22/2021	01/17/2021	XXXXX
20210220196	XXXXXXX XXXXX	0	01/16/2021	MALE	1/22/2021	01/17/2021	XXXXX
20210220197	XXXXXXX XXXXX	0	01/14/2021	FEMALE	1/22/2021	01/15/2021	XXXXX
20210220199	XXXXXXX XXXXX	0	01/14/2021	MALE	1/22/2021	01/16/2021	XXXXX
20210220200	XXXXXXX XXXXX	0	01/14/2021	MALE	1/22/2021	01/16/2021	XXXXX
20210220202	XXXXXXX XXXXX	0	01/14/2021	MALE	1/22/2021	01/16/2021	XXXXX
20210220203	XXXXXXX XXXXX	0	01/15/2021	FEMALE	1/22/2021	01/16/2021	XXXXX
20210220204	XXXXXXX XXXXX	0	01/14/2021	FEMALE	1/22/2021	01/16/2021	XXXXX
20210220205	XXXXXXX XXXXX	0	01/15/2021	MALE	1/22/2021	01/16/2021	XXXXX

XXXXXXXXXXXXXX
Laboratory Manager

XXXXXXXXXXXXXX
Unit Head

This is a computer-generated report. Signature is not required.

Annex 19. NBS Results (Outside Normal Limits)

Individual Result (Outside Normal Limits)

Newborn Screening Center
Address 1
Address 2
Contact Details

Report run date: January 29, 2021

ATTENTION:

Name of Hospital of Collection:
XXXXXXXXXXXXXXXXXXXX
Address of Hospital: XXXXXXXXXXXXXX

Name of NBS Coordinator:
XXXXXXXXXXXXXX

LEGEND:

Remarks	Instructions
Within Normal Limits	Normal result for the screened disorder.
Outside Normal Limits*	Positive on screening test, confirmatory test must be done immediately. Kindly refer your patients to the confirmatory center nearest your area.

Sample ID	Mother's Name	Multiple	Date of Birth	Sex	Date Received	Date of Collection	Physician
20210220089	XXXXXXXXXXXXXX	0	01/13/2021	FEMALE	01/22/2021	01/14/2021	XXXXXXX

DISORDERS	REMARKS
Congenital Hypothyroidism (CH)	Within Normal Limits
Congenital Adrenal Hyperplasia (CAH)	Within Normal Limits
Galactosemia (TG)	Within Normal Limits
Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD)	Outside Normal Limits*
Amino Acid Disorders (AA)	Within Normal Limits
Organic Acid Disorders (OA)	Within Normal Limits
Fatty Acid Disorders (FAO)	Within Normal Limits
Biotinidase Deficiency (BTND)	Within Normal Limits
Cystic Fibrosis (CF)	Within Normal Limits
Urea Cycle Disorders (UC)	Within Normal Limits
Hemoglobinopathies (HGB)	Within Normal Limits

G6PD Confirmatory Centers	Address	Contact Numbers	Contact Person/s

XXXXXXXXXXXXXX
Laboratory Manager

XXXXXXXXXXXXXX
Unit Head

This is a computer-generated report. Signature is not required.

Summary Report (Outside Normal Limits)

Newborn Screening Center
Address 1
Address 2
Contact Details

Report run date: January 29, 2021

ATTENTION:

Name of Hospital of Collection:
XXXXXXXXXXXXXXXXXXXX
Address of Hospital: XXXXXXXXXXXXXX

Name of NBS Coordinator:
XXXXXXXXXXXXXX

LEGEND:

Remarks	Instructions
Outside Normal Limits*	Infant may be at risk for an inborn error of metabolism. Urgent repeat collection is required.
Within Normal Limits	Normal result for the screened disorder.

Sample ID	Mother's Name	Multiple	Date of Birth	Sex	Date Received	Date of Collection	Physician
20210220089	XXXXXXXXXXXXX	0	01/13/2021	FEMALE	01/22/2021	01/14/2021	XXXXXXX

DISORDERS	REMARKS
Congenital Hypothyroidism (CH)	Within Normal Limits
Congenital Adrenal Hyperplasia (CAH)	Within Normal Limits
Galactosemia (TG)	Within Normal Limits
Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD)	Within Normal Limits
Amino Acid Disorders (AA)	Within Normal Limits
Organic Acid Disorders (OA)	Within Normal Limits
Fatty Acid Disorders (FAO)	**Outside Normal Limits***
Biotinidase Deficiency (BTND)	Within Normal Limits
Cystic Fibrosis (CF)	Within Normal Limits
Urea Cycle Disorders (UC)	Within Normal Limits
Hemoglobinopathies (HGB)	Within Normal Limits

XXXXXXXXXXXXXX
Laboratory Manager

XXXXXXXXXXXXXX
Unit Head

This is a computer-generated report. Signature is not required.

Annex 20. Parent Refusal on Confirmatory Form

English

National Comprehensive Newborn Screening System

REFUSAL FORM
FOR CONFIRMATORY TEST

Date: _____

The Newborn Screening Act of 2004 (Republic Act 9288) states that newborns found positive in any of the metabolic disorders through the newborn screening must undergo confirmatory testing. It is a process of verifying the newborn screening **positive** result.

The following were explained to me:

- ☑ The difference between newborn screening and confirmatory testing
- ☑ The procedure of confirmatory testing
- ☑ The health facilities which are offering confirmatory testing
- ☑ The benefits of undergoing confirmatory testing
- ☑ The disadvantage of not undergoing confirmatory testing

Despite these, as parent/guardian of _____,
(Name of patient/Newborn)
I refuse to have confirmatory done for reasons known only to me.

I declare with full knowledge and competence that this institution, _____ and health workers therein shall be free
(Name of the Institution)
from all liabilities under the law because this refusal for confirmatory testing is my decision.

I understand that a copy of this dissent form shall be part of the permanent medical records of my child/ward and will be part of a national registry/database of the National Comprehensive Newborn Screening System.

_____
Signature over Printed Name of Parent/Guardian

Witness/es:

_____
Signature over Printed Name/Designation

Filipino

National Comprehensive Newborn Screening System

KASULATAN NG PAGTANGGI
SA CONFIRMATORY TEST

Petsa: _____

Nakasaad sa Newborn Screening Act of 2004 (Republic Act 9288) na ang sanggol na positibo sa alinman sa mga *metabolic disorders* matapos ang *newborn screen* ay kailangang dumaan sa *confirmatory testing*. Ito ay isang pamamaraan ng pagtiyak sa positibong resulta ng *newborn screening*.

Ipinaliwanag sa akin ng pasilidad ang mga sumusunod:

- ☑ Ang pagkakaiba ng *newborn screening* at *confirmatory testing*
- ☑ Ang pamamaraan ng *confirmatory testing*
- ☑ Kung anong mga pasilidad ang nagsasagawa ng *confirmatory testing*
- ☑ Ang benepisyo ng pagpapa-*confirmatory testing*
- ☑ Ang pinsala na maaaring isulot ng hindi pagpapa-*confirmatory testing* ng bagong panganak na sanggol

Sa kabila nito, tumatanggi pa rin ako bilang magulang/tagapangalaga na ipa-*confirmatory test* ang anak/sanggol na si _____ sa mga kadahilang ako lamang ang nakakaalam.
(Pangalan ng Sanggol)

Sa aking sapat na kaalaman at kakayahan, walang pananagutan sa batas ang institusyong ito, _____at ang mga
(Pangalan ng Institusyon)
nagtatrabaho dito sa aking desisyong hindi ipa-confirmatory test ang sanggol.

Naunawaan ko na ang kopya ng kasulatan ng pagtangging ito ay magiging parte ng permanenteng rekord ng aking anak/sanggol sa aking pangangalaga at magiging bahagi din ng database ng *National Comprehensive Newborn Screening System*.

_____
Pirma sa ibabaw ng Pangalan ng Magulang/Tagapangalaga

Mga Testigo:

_____
Pirma sa ibabaw ng Pangalan/Designasyon

Annex 21. Performance Evaluation and Assessment Scheme for NSF

Philippine Performance Evaluation and Assessment Scheme

PPEAS for Newborn Screening Facilities*

NSF Program Review
Newborn Screening Reference Center
National Institutes of Health, UP Manila

** Based on the PEAS (version 8/25/06) developed by Health Resources and Services Administration, Maternal and Child Health Bureau, Genetic Services Branch, and National Newborn Screening and Genetics Resource Center, Department of Pediatrics, The University of Texas Health Science Center at San Antonio.*

Version: 09 December 2016

COMPONENTS

1. Existence of a Newborn Screening Program in the Health Facility
2. Existence of an Effective Newborn Screening Team
3. Facility Support
4. Administrative support for NBS Implementation
5. Quality Improvement of NBS
6. Reporting: Quarterly Submission to Regional Office
7. Other Remarks

Evaluation of the Newborn Screening Program Implementation at the Newborn Screening Facilities (NSFs)

To ensure the quality and sustainability of the Newborn Screening system, the Newborn Screening Reference Center and the DOH Regional Offices are conducting an evaluation of the Newborn Screening Facilities (NSFs). This evaluation tool aims to determine the factors at play in the NBS implementation, particularly the problems which impact on achieving DOH's goal of "every parent informed, every newborn screened, every health facility equipped and with health practitioner trained to provide newborn screening service". Results of this evaluation will be the basis for recommendations to improve the implementation of the NBS program in your health facility, and in all Newborn Screening Facilities.

Thank you for your cooperation.

Hospital Code:	**Name of NSF:**
Printed Name and Signature:	**Date Accomplished:**
Complete Address (Please also indicate ZIP Code):	
Contact Numbers:	

I. Existence of a newborn screening program in the health facility	YES	NO	REMARKS
1. DOH-NIH certificate exists as proof that the facility offers NBS services.			
2. Issuances from NSC, DOH, NSRC are available.			
3. Signage exists informing the public that NBS services are available.			
4. The health facility has a copy of the NSC Administrative Mechanics			
5. The NBS service is offered/available 24/7.			
6. NBS is included in the orientation of all employees in the health facility.			
7. Any case of refusal for religious reasons is documented.			
8. Any refusal for reasons other than religion are documented.			
9. A written protocol exists describing in detail all the procedures involved in			

FO-PPEAS-03

	newborn screening			
		YES	NO	REMARKS
10.	Specimen collection procedure is followed.			
a)	informing the patient about NBS			
b)	Ensuring completeness, accuracy and legibility of patient information.			
c)	Identifying the patient correctly			
d)	Properly and legibly filling of the collection card			
e)	Collecting an acceptable heel prick specimen.			
f)	Proper drying of blood spots before shipment.			
g)	Proper packing and shipping specimens.			
h)	Documenting date and time of specimen shipment.			
i)	Record-keeping to document that testing and follow-up occurred.			
j)	Receiving results and releasing results to parents			
k)	Acting on results when appropriate			
11.	A client educational program exists that may include:			
a)	NBS posters in strategic locations			
b)	Mechanism for viewing video clips			
c)	Mothers' classes/bench conferences			
d)	NBS pink brochures			
II.	**Existence of an Effective Newborn Screening Team**	**YES**	**NO**	**REMARKS**
1.	The health facility has a working NBS Team composed of at least:			
a)	A trained NBS Coordinator			
b)	A trained assistant NBS Coordinator			
2.	At least one person is trained in and responsible for:			
a)	proper sample collection			
b)	releasing of result			
c)	tracking of patients			
III.	**Facility Support**	**YES**	**NO**	**REMARKS**
1.	An area designated for drying specimen collected			
2.	NBS collection kits are available at all times and are stored in a clean and dry			

environment.			
3. Facility is maintaining at least one-month supply of cards.			
	YES	**NO**	**REMARKS**
4. Secured and confidential logbook/information system of patients is maintained.			
i. Information system includes:			
a) Patient Information (mother's name, baby's surname)			
b) Date specimen is collected			
c) Date sent to NSC			
d) Result Information (date received and released)			
ii. Logbook of positive patients includes:			
a) Patient Information (mother's name, baby's surname and disorder)			
b) Date and time of recall			
5. Abnormal results are relayed to the parents within 24 hours from the receipt of result from the NSC			
6. A secure and confidential system for NBS result is maintained.			
7. A detailed protocol for recalling patients exists.			
8. The system include a mechanism for seeking assistance from:			
i. NSC. If yes how many times?			
ii. DOH. If yes how many times?			
iii. LGU. If yes how many times?			
IV. Administrative support for NBS implementation	**YES**	**NO**	**REMARKS**
A scheme is provided in addressing service delivery for indigent patients			
V. Quality improvement of NBS			
1. The health facility management has an annual quality assessment of the status of the NBS program			
2. The NBS team conducts a quarterly assessment that includes:			
i. Review of specimen cards quality			
ii. Problems encountered			
iii. Timeliness of collection, submission and reporting			
iv. Coverage			
VI. Reporting: Quarterly submission to Regional Office	**YES**	**NO**	**REMARKS**
1. Livebirths			

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2. Number of screened			
3. Number of refusals			
VII. Other Remarks			
Printed Name and Signature:		**Date accomplished:**	

G6PD Brochure

G6PD Deficiency

Glucose-6-phosphate dehydrogenase deficiency, or G6PD deficiency, is the most common enzyme deficiency worldwide. Know more about it to protect your baby.

www.newbornscreening.ph
Newborn Screening Reference Center,
National Institutes of Health,
University of the Philippines Manila

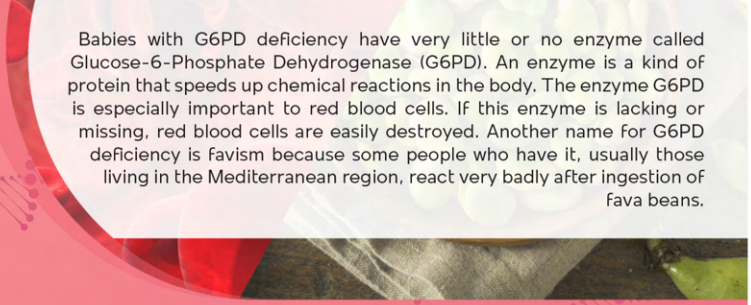
PhilHealth
Your Partner in Health

WHAT IS G6PD DEFICIENCY?

% **According to statistics, about 400 million people have G6PD deficiency, and it is most common in Africa, Southeast Asia and the Middle East. In the Philippines, data from the Newborn Screening Reference Center from 2004-2021 showed that 1 out of 63 newborn Filipinos have Glucose 6 Phosphate Dehydrogenase deficiency.**

Glucose-6-phosphate dehydrogenase deficiency, or G6PD deficiency for short, is the most common enzyme deficiency worldwide. This is an x-linked inherited disorder which means that from the time a baby is born, there is already something wrong with how his body makes and breaks important substances.

Babies with G6PD deficiency have very little or no enzyme called Glucose-6-Phosphate Dehydrogenase (G6PD). An enzyme is a kind of protein that speeds up chemical reactions in the body. The enzyme G6PD is especially important to red blood cells. If this enzyme is lacking or missing, red blood cells are easily destroyed. Another name for G6PD deficiency is favism because some people who have it, usually those living in the Mediterranean region, react very badly after ingestion of fava beans.



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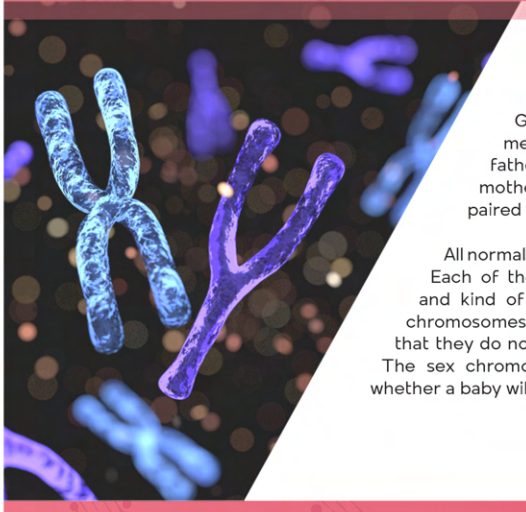
What causes G6PD deficiency?

In order to understand what causes G6PD deficiency, one must first learn a bit about genes and chromosomes. Genes are like the body's blueprints. They contain instructions on how specific parts of the body are made.

For example, if the instructions in your hair genes say your hair is black, your hair will be black. Genes are packaged into threadlike structures called chromosomes. A chromosome is very much like a beaded bracelet. The beads are the different genes that give instructions for different parts of the body; the entire bracelet is the chromosome.



Genes usually come and act in pairs. One member of a specific pair comes from the father, and the other member comes from the mother. The members of a pair are located on paired chromosomes.

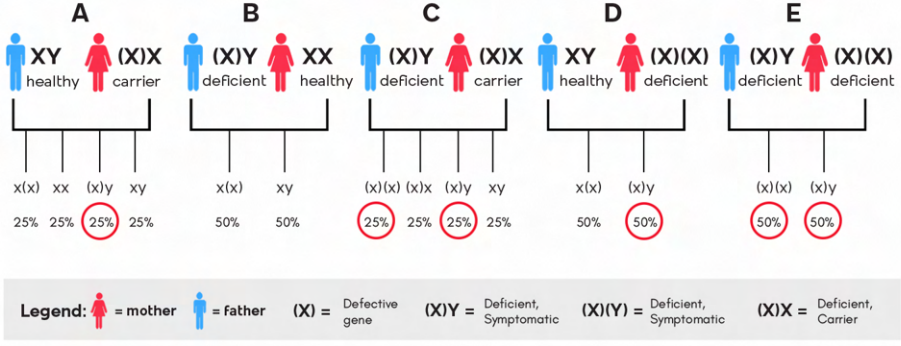
All normal human beings have 23 pairs of chromosomes. Each of the first 22 pairs contains the same number and kind of genes. The last and 23rd pair is the sex chromosomes. They are different from the first 22 pairs in that they do not have the same number and kind of genes. The sex chromosomes contain the genes that determine whether a baby will be a girl or a boy.

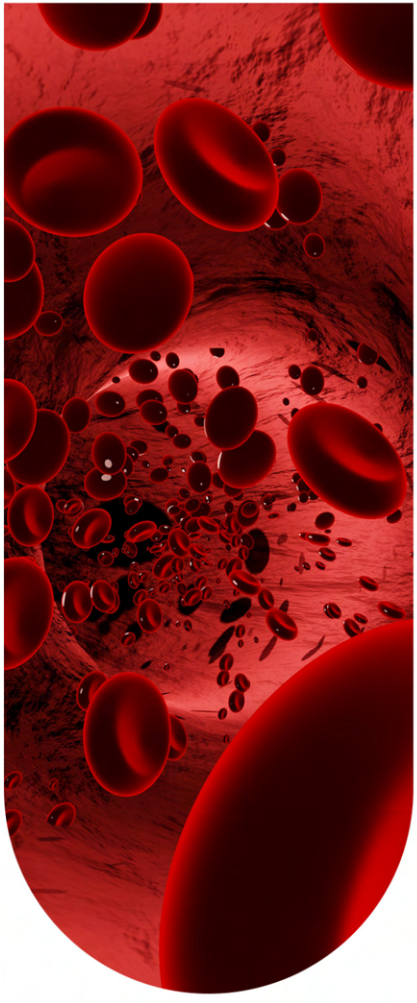
THE G6PD GENE

All baby girls have two X chromosomes. All baby boys have one X and one Y. The gene that gives instructions on how G6PD is made is found in the X chromosome only, thus G6PD deficiency is described as X-linked.

If a baby girl gets one defective G6PD gene from either of her parents, she will not have G6PD deficiency because she has another G6PD gene that can do the work (remember: a baby girl has two X chromosomes, thus two G6PD genes). But if she gets two defective G6PD genes from both her parents, she will have G6PD deficiency. On the other hand, a baby boy whose G6PD gene is defective will surely get G6PD deficiency because the Y chromosome has no G6PD gene. A defective G6PD gene will give wrong instructions on how to make the enzyme G6PD. As a result, too little or none of it is made.

Inheritance of G6PD Deficiency





G6PD has a very small but strategic role in protecting the body from substances that can cause damage to cells or oxidative substances. Because of this important role, G6PD is normally found in all parts of the body. To be sure, most parts of the body also keep a "spare" enzyme, one that can do the work of G6PD in case it is lacking or missing entirely. Unfortunately, this is not the case with red blood cells. They do not have spare enzymes that can do the work of G6PD. If a baby does not have enough G6PD, his red blood cells lack protection from the harmful effects of oxidative substances.

What are the RISKS FOR AN INDIVIDUAL with G6PD Deficiency

A baby with G6PD deficiency appears and remains healthy until he is exposed to a large amount of oxidative substances. When this happens, his red blood cells are destroyed, a process known as hemolysis. Red blood cells carry oxygen to all parts of the body. When they undergo hemolysis, the baby will have hemolytic anemia. The signs and symptoms of hemolytic anemia are paleness, dizziness, headache, tea-colored urine, and abdominal or back pain or both. Hemolytic anemia, when very severe, can end in death.

Destroyed red blood cells are brought to the liver to be broken down to smaller pieces for disposal. One of the end products of this process is bilirubin, a yellowish substance that accumulates in different parts of the body when too much of it is produced. Quite often, bilirubin accumulates in the skin and causes it to appear yellowish. In the worst cases, bilirubin accumulates in the brain and causes mental retardation or death.

WHERE DO OXIDATIVE SUBSTANCES COME FROM?

Hemolysis of red blood cells will only occur IF and WHEN a G6PD deficient child is exposed to oxidative substances. Oxidative substances are found in certain drugs, foods, and beverages. The body also produces oxidative substances during severe infections or illnesses such as typhoid fever, pneumonia, or kidney failure. **Most drugs with strong oxidative effects are of these kinds:**

1. antibiotics of the sulfa group

2. medicines for malaria

3. some medicines for fever

For a more detailed list of drugs, food, and beverages with strong oxidative substances, please refer to page 9 and 10.

How is G6PD deficiency treated?

When a child has taken oxidative substances and suddenly shows the signs and symptoms of hemolytic anemia, he is said to have a hemolytic crisis. During such crisis, the goal of doctors and nurses is to prevent the harmful effects from getting worse. Blood transfusion, oxygen, and folic acid may be given. The ultimate treatment for G6PD deficiency is gene therapy (replacing a defective gene with a good one), but this is not yet available at the present time.

As a parent, how do I prevent a HEMOLYTIC CRISIS?

1. **Tell your child's pediatrician that your child has G6PD deficiency.** This is very important so that he will not prescribe oxidative drugs in case your child gets ill. He would also be able to watch out for hemolytic crisis and would immediately know what to do just in case it happens.
2. **Keep your list of oxidative substances in a handy place.** Better yet, post it in a convenient spot on the kitchen wall. Always double-check food, beverage, & medicine labels against the list.
3. **Memorize the signs and symptoms of hemolytic anemia:** paleness, dizziness, headache, difficulty in breathing, rapid and strong heartbeats, tea-colored urine, and abdominal or back pain. Bring your child to his pediatrician as soon as these signs and symptoms appear.
4. **Do not ignore infections.** Persistent fever signals an infection. Bring the child at once to his pediatrician.
5. As your child gets older, **honestly and gently tell him about his condition** and teach him to be careful about what he eats.

My baby did not go through newborn screening. What should I do to make sure that he/she is not G6PD deficient?

You can bring your child to a pediatrician for a thorough medical check up. If the age of your baby is already beyond the limit for newborn screening, he/she can still undergo confirmatory testing for G6PD deficiency. However, for the other diseases included in the newborn screening, it will depend on the assessment of your pediatrician if your baby will need a referral to an endocrinologist or geneticist for further evaluation.

FAQs

My baby has G6PD deficiency and I feel devastated. Did I do something wrong when I was pregnant? Could I have done something while I was pregnant for my baby to avoid it?
You did nothing wrong. It is a genetic disorder, hence, there is nothing you can do as a mother to prevent it.

My firstborn was diagnosed with G6PD deficiency. I am pregnant again and worried — will my next baby also have it?
Once you have a child with G6PD deficiency, there is always a possibility of having a child with G6PD deficiency for every succeeding pregnancies. All your babies must undergo newborn screening.

Even if tested positive by Newborn Screening Test, is it possible that the confirmatory test of my child is negative?
Yes. If negative, then you do not have to worry about the medicines and the food items. If positive, make sure that your attending physician knows that your child has G6PD deficiency.

I am a parent. Should I get tested for G6PD deficiency?
Yes, you may want to have yourself tested by requesting for G6PD assay using the confirmatory test in designated confirmatory centers. However, only males who are G6PD deficient and affected females (homozygous for G6PD) can be identified. A female with a carrier status (heterozygous for G6PD) cannot be detected by this kind of test.

I am trying to conceive. Should I be tested for G6PD deficiency?
It is your choice if you want to be tested but the probability of having a child with G6PD deficiency does not solely depend on your status. Your spouse's G6PD status can also affect the probability of having a child with G6PD. It will be more practical to just have your newborn baby undergo the routine newborn screening after birth.

Where is G6PD Deficiency Confirmatory Testing done?
At the moment, there are 30 Confirmatory Testing Centers in the country. You may want to contact them directly regarding their testing schedule. Please visit www.newbornscreening.ph for details.

Is formula milk safe for my son who has G6PD deficiency?
Although soya and soy lecithin are both included in the list, many products contain very small amount of soya including the common milk formulas. There has not been any report of hemolysis due to milk products containing soya. Soy lecithin, which is present in different brands, is an important component of milk but it does not make up the whole milk. REMEMBER: Breastfeeding is still best for babies. Breastfeeding is healthier for both babies and mothers.

I am breastfeeding my son. When I haven't received the newborn screening result I ate the food that need to be avoided. Will they take effect on my son?
Theoretically, food and chemicals can be excreted through the milk. If your son did not develop hemolysis due to that event in the past, then probably they were not excreted at all through the milk or the amount was too small to cause significant reactions.

I have donated blood several times without knowing I am a G6PD carrier. Can I still donate blood?
Yes, you may still donate. There is no contraindication as a person with G6PD deficiency. There is also no policy written that you cannot donate.

Is it transmissible via blood transfusion?
No, it is not transmissible via blood transfusion.

My baby has G6PD deficiency; vitamins are on the restricted list. How can I keep him healthy?
Multivitamins are generally not contraindicated. Vitamin C or ascorbic acid can be given for as long as the dose is within the recommended dosage. Multivitamins are considered food supplements, BUT there is no substitute to nutritious, freshly prepared food and a well-balanced diet.

Is it okay to eat chocolates even if they have soy content?
Although soya is included in the list, many products contain very small amount of soya. So generally patients with G6PD deficiency can eat chocolates except if it is a fava bean coated with chocolates. Please read the product label.

Is malunggay leaves safe to eat? Because I read in some website that malunggay isn't safe for people with G6PD deficiency.
For as long as it is not included in the official list of NIH as foods to avoid, then there is no basis to withhold malunggay from persons with G6PD deficiency.

I have a son who has G6PD deficiency and now he has a cold and cough, it is safe to use oregano for his medication?
Since oregano is not included in the list, it can be given. However, you should exercise caution in giving commercially produced herbal preparations because they might contain unreported chemicals. Generally, cough and colds can be treated with lots of fluids. If signs and symptoms persist or worsen, consult your doctor.

Is infant cereal safe for newborns with G6PD deficiency?
So far, there are no reported cases of hemolysis secondary to rice infant cereals (eg Cerelac). It contains a very small amount of soya in the first place.

Is insect repellant safe to use?
If you are not comfortable in using insect repellant, you can look for an organic type. If not available, you can just apply the commercial ones on your baby's clothes.

What toothpaste brand is safe for babies with G6PD?
The amount of menthol that is in ordinary toothpastes so far has not caused hemolysis in patients with G6PD deficiency.

What about blueberries? In other countries, they are not listed as contraindicated food.
If there is confusion about blueberries then it might be best to avoid it until extensive evidence that it is safe for patients with G6PD deficiency becomes available. Please note that patients with G6PD deficiency are not the same all over the world because of differences in mutations and therefore phenotypes, some of them will react consistently with some of the items in the list and some would not.

What are the signs of hemolysis?
Signs of hemolysis include tea colored urine, discoloration of the eyes and skin, weakness, and irritability. A child may look clinically pale but may actually have normal CBC results. So a CBC should be requested to confirm if the child has anemia.

My son exhibited symptoms of a viral infection (vomiting, lbm, lack of appetite). I saw on his diaper that the stain of his urine is somewhat tea colored. Should I be worried? What should I do?
Bring him to his pediatrician for check up. Please do CBC APC, and urinalysis. Check for urine hemoglobin.

Have there been reported cases of hemolysis here in the Philippines because of G6PD deficiency? If so, what were the most common causes?
Yes, there have been reports of hemolysis among patients with G6PD deficiency. There are also claims registered at PhilHealth. Some of the causes of hemolysis recorded in Philippine Children's Medical Center are infections (Flu, hepatitis) and exposure to moth balls. Fortunately, none of these patients died because of severe anemia. They were brought immediately to the hospital as soon as the initial signs of hemolysis became evident

What are the chances of getting a different result if we undergo another Confirmatory Test?
The family of a child confirmed with G6PD deficiency may always opt to have another confirmatory test if they are having doubts. If the result is below the borderline, the patient will most likely get a positive result in another test.

As a mom, can I use menthol-containing products?
The use of menthol and camphor containing products are not recommended if the goal is to reduce or eliminate the pain. These products only divert attention away from the painful area by producing cooling effects and sensation on the skin. It is always better to know the real cause/s of the pain/discomfort by consulting your doctor about it.

Is there a contraindication to any vaccination for patients with G6PD deficiency?
None.

DRUGS TO BE AVOIDED

As of January 2021

A. Antibacterial
**Nalidixic acid*
Nitrofuran
1. Nitrofurantoin
2. Furazolidone
3. Nitrofurazone / nitrofural
(Common Brand Names: Macrodantin Diafuran, Diapectolin, Furoxone, Furacin)
**P- aminosalicylic acid*

B. Analgesic/ Antipyretic
**Acetanilid*

C. Antihelmentic
**B-naphthol*
**Niridazole*
**Stibophan*

D. Sulfonamides and Sulphones
Dapsone (Common Brand Name: Lepravir)
**Glucosulphone sodium*
Glyburide/Glibenclamide (Common Brand Name: Euglucon, Gluban, Lodulce, Orabetic)
**Mafenide acetate*
**Salicylazosulphapyridine/Sulfasalazine*
Stibophen (Common Brand Name: 2-(2-Oxido-3,5-Disulphonatophenoxy)-1,3,2, Benzodioxastibole-4-6-Disulphonate)
**Sulphadimidine*
**Sulphafurazone*
Sulphamethazole/Sulfamethazole
(Common Brand Name: Bacidal, Bactille Forte, Bactrim, Bacxal, DLI Cotrimoxazole, Forteprim, Globaxol, Pharex Cotrimoxazole, Ritemed Cotrimoxazole, Septrin, Trim S)
Sulphanilamide/ Sulfanilamide
Sulphapyridine
**Sulphoxone/ Sulfoxone*
Sulfasalazine, Salazosulfapyridine
(Common Brand Name: Salazopyrin)

E. Antimalarials
Chloroquine
(Common Brand Name: Aralen, Chlorofoz)
**Pamaquine*
Primaquine
Pentaquine

F. Miscellaneous
Acetylphenylhydrazine
Dimercaprol
Futamide
Isobutyl nitrate
Mepacrine
Phenazopyridine (Common Brand Name: Azomir)
Probenecid
Thiazolesulfone
Urate oxidase/ Rasburicase

You may visit www.newbornscreening.ph to check for updates on these lists

DRUGS SAFE TO TAKE IN THERAPEUTIC DOSES

Acetaminophen (Paracetamol, tylenol)
Acetophenetidin/ phenacin
Aspirin/ Acetylsalicylic acid (Alka-seltzer, Aspilets, Cor-80, Cortal)
Ascorbic acid
Chloramphenicol (Chlormycetin, Chloro-S, Chlorsig, Klorfen, Oliphenicol, Optomycin, Pediachlor, Penachlor Speradex)
Ciprofloxacin (Ciprobay, Clpromax, Cipromet, Qinosyn-500, Quilox, Xipro)
Diphenhydramine
Isoniazid
Phenytoin
Quinidine
**Vitamin K analogues/Phytomenadione
(Hema-K, Konakion MM, Phil Pharmawealth/Atlantic Phytomenadione)

NOTE:

*Not available in the Philippines

**Should be water soluble

TO BE AVOIDED

IMPORTANT REMINDERS FOR PATIENTS WITH G6PD DEFICIENCY

1. Avoid ingestion of or exposure to the listed drugs and chemicals.
2. If you have cough, colds, or other bacterial or viral infections, make sure to inform your doctor that you have G6PD deficiency.
3. If you have ingested or were exposed to any medication and your urine became tea-colored, inform your doctor immediately.
4. If you have yellowish discoloration of skin, sclera or any part of your body, consult your doctor immediately.

CHEMICALS

- Methylene Blue
- Arsine
- Phenylhydrazine
- Toluidine blue
- Trinitrotoluene
- Aniline dyes

FOOD AND DRINKS

- Fava beans (Dingdong nuts, Mr. Bean)
- Red wine
- Legumes (Abitsuelas, Garbanzos, Kadyos, Munggo)
- Blueberry
- Soya food (Taho, Tokwa, Soy Sauce)
- Tonic water
- Bitter melon/ampalaya

OTHERS

- Menthol (Alaxan Gel, Ben-gay, Efficascent Oil, Listerine Mouthwash, Listerine Pocketpacks Megascent Oil, Mentopas Medicated, Plaster, Omega Pain Killer)
- Camphor (Liniments)
- Naphthalene (Moth balls)
- Parabenzene dichloride / dichlorobenzene (Toilet deodorizer)
- Henna
- Herbs (Cattle gallstone bezoar, Honeysuckle flower, Chimonanathus flower, 100% pearl powder Figwortflower, Acalypha indica)

G6PD Confirmatory Centers

As of Dec 2022

	CENTER	ADDRESS	CONTACT
CAR			
1	**Baguio General Hospital and Medical Center**	Gov Pack Rd., 2600 Baguio City	09332003296
REGION 1			
2	**Ilocos Training and Regional Medical Center**	Parian, San Fernando City, La Union	09778108778
3	**Mariano Marcos Memorial Hospital & Medical Center**	Brgy. 6, San Julian City of Batac, Ilocos Norte	(077) 600 8000
4	**Region 1 Medical Center**	Arellano Street, Poblacion Oeste Dagupan City	(075) 515-8916
REGION 2			
5	**Cagayan Valley Medical Center**	#2 Dalan na Pagayaya Carig Sur, Tuguegarao City	(078) 302 0000
REGION 3			
6	**Angeles University Foundation Medical Center**	Mac Arthur Hi-way, Angeles City	09562943730
7	**Bataan General Hospital and Medical Center**	Manahan St., Tenejero, Balanga City	(047) 237-1275 loc 6704
REGION 4-A			
8	**Lipa Medix Medical Center**	J.P. Laurel Highway, Balintawak, Lipa City	09338526522; 09611191788
9	**University of Perpetual Help Dr. Jose G. Tamayo Medical Center- Binan (Perpetual Help Medical Center-Biñan)**	National Highway, Sto. Niño, Biñan City, Laguna	(02) 8779 5310; (049) 544 5150 loc 2033

G6PD Confirmatory Centers

As of Dec 2022

	CENTER	ADDRESS	CONTACT
REGION 4-B			
10	**Palawan Medical Mission Group Multipurpose Cooperative**	Corner Burgos & Mabini Sts., Puerto Princesa City, Palawan	09989565102
NCR			
11	**Manila Central University-Dr. Filemon D. Tanchoco Sr. Medical Foundation, Inc.(MCU-FDTMF, INC.)**	Samson Road, EDSA, Caloocan City	(02) 8363 3084
12	**Our Lady of Lourdes Hospital**	46 P. Sanchez St., Sta Mesa Manila	(02) 8716 3901 loc 3399/3396/3397; 09218528516
13	**The Medical City**	Ortigas Avenue, Pasig City, Metro Manila	(02) 8988 1000 loc 6125; 8635-6789 loc 6125
14	**University of Perpetual Help Dalta Medical Center**	#2 Dalan na Pagayaya Carig Sur, Tuguegarao City	(02) 8874 8515 loc 153; 88748515 loc 151
REGION 5			
15	**Bicol Regional Training and Teaching Hospital**	Rizal St. Legazpi City Albay	(052) 483 1088; 483 0806
16	**Bicol Region General Hospital and Geriatric Medical Center**	San Pedro, Cabusao, Camarines Sur	09637045263
REGION 6			
17	**West Visayas State University Medical Center**	E. Lopez St., Jaro, Iloilo City	(033) 320 2431 loc 108/138
18	**Dr. Pablo O. Torre Memorial Hospital**	B.S. Aquino Drive, Bacolod City 6100, Negros Occidental	09988460620

G6PD Confirmatory Centers

As of Dec 2022

	CENTER	ADDRESS	CONTACT
REGION 7			
19	**Cebu Doctors' University Hospital**	Osmeria Boulevard Capitol Site, Cebu City 6000	(032) 255 5555
20	**Gov. Celestino Gallares Memorial Hospital**	M. Parras St., Tagbilaran City, Bohol	(038) 411 4868; 411 4869
21	**Silliman University Medical Center**	V. Aldecoa, Daro, Dumaguete City, 6200	09453902877
REGION 8			
22	**Eastern Visayas Regional Medical Center**	Brgy. Bacagay, Tacloban City	(053) 833 5309; 09771178444
REGION 9			
23	**Brent Hospital**	R.T. Lim Blvd. Zamboanga City	09953273022
REGION 10			
24	**Cagayan De Oro Polymedic Medical Plaza**	Kauswagan Highway, Cagayan De Oro City	09173051163, 09688523615
25	**La Vina General Hospital**	L. Alkuiro St. Valencia City, Bukidnon	09976058050
26	**Mayor Hilarion A. Ram I ro Sr. Medical Center**	Maningcol, Ozamiz City	(088) 521 0440
REGION 11			
27	**Tagum Doctors Hospital**	Highway SA Rabe Subd., Tagum City	09195451830
28	**Davao Medical School Foundation Hospital**	DMSF Drive, Bajada, Davao City	09266887834
REGION 12			
29	**General Santos Doctors Hospital**	National Highway, General Santos City	09338162793
30	**Kidapawan Doctors Hospital**	Quezon Blvd. Kidapawan City	09237234746

Annex 23. Relevant Clinical Information

TSH

1. Trisomy 21/Down Syndrome
2. Family history of Congenital Hypothyroidism (CH)
3. Maternal thyroid disease (e.g. Grave's disease, Hypothyroidism, Thyroid cancer)
4. Mother under thyroid medication (e.g. L-thyroxine, Methimazole, Carbimazole, Proplythiouracil)
5. Same sex twin with elevated TSH result
6. Clinical manifestations of CH or hypopituitarism (e.g. micropenis, undescended testes, hypoglycemia, prolonged jaundice, failure to thrive)

17OHP

1. Atypical genitalia
2. Family history of CAH
3. Family history of neonatal death

GAL

1. Family history
   - Childhood cataract
   - Siblings with known GAL disorder
2. Failure to thrive
3. Poor suck, cry and activity
4. Jaundice
5. Liver dysfunction
6. Sepsis-like presentation with any of the following:
   - Family history of childhood cataract
   - Failure to thrive
   - Jaundice
   - Liver dysfunction

MSMS

1. Seizure
2. Family history of disorder
3. Hypoglycemia
4. Coma
5. Poor suck
6. Unusual urine smell

BTND

1. Seizures
2. Hypotonia
3. Skin rashes (erythematous dermatitis)
4. Alopecia

HPLC

1. Generalized edema and pallor (features of hydrops fetalis)
2. Jaundice at less than 24 hours of life
3. Family history
   - Pallor/red cell blood transfusion/hemoglobinopathy/ thalassemia
   - Previous pregnancies resulting in stillbirth or hydrops fetalis
   - Early gallstone formation among family members (less than 40 years old)

G6PD

1. History of early gallstone formation in the family (less than 40 years old)
2. History of sudden jaundice with anemia in the family
3. History of prolonged anemia in the family
4. Neonatal jaundice within 24 hours of life

IRT

1. Known carrier or family history of CF
2. Meconium ileus (failure to pass meconium before 24 hours)
3. Salty sweat; many parents notice a salty taste when kissing their child
4. Greasy, smelly stools that are bulky and pale colored
5. Poor growth and weight gain (failure to thrive)*
6. Recurrent coughing, wheezing or pneumonia episodes*

*late manifestations

REFERENCES

NCNBSS Manual of Operations, 2004
www.newbornscreening.ph

CONTRIBUTING AUTHORS/EDITORS