



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

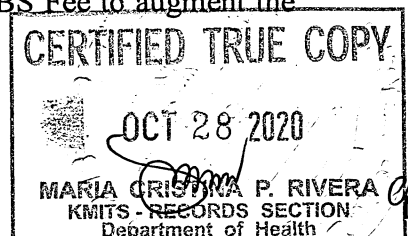
Republic Act 9288, otherwise known as “the Newborn Screening Act of 2004, provides for the establishment of a national comprehensive newborn screening system that includes (i) education of relevant stakeholders; (ii) screening, recalling and diagnosis of patients; (iii) provision of medical/dietary/surgical 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:



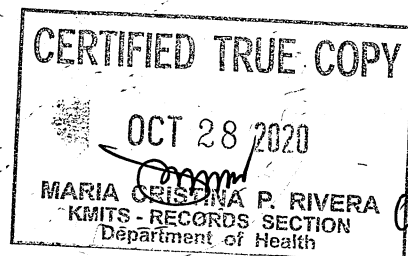
1. Implementation of the Expanded Newborn Screening Program;
2. Expansion of the National Comprehensive Newborn Screening System (NCNBSS) with the establishment of the Centers for Human Genetics Services (CHGS).
3. Allocation and utilization of a portion of the ENBS funds for the operation of the CHGS and for the management (diagnostic and therapeutic) of patients.

III. SCOPE OF APPLICATION

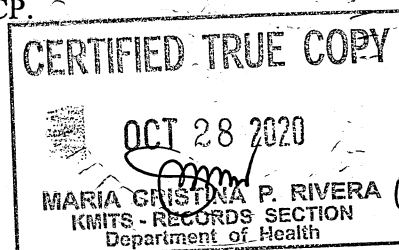
This Order shall apply to all DOH-Centers for Health Development (CHD), Ministry of Health (MOH) Bangsamoro Autonomous Region in Muslim Mindanao (BARMM), Newborn Screening Centers (NSCs), Newborn Screening Reference Center (NSRC), Institute of Human Genetics, Newborn Screening Facilities (NSFs), and 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, sanitarium, 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.



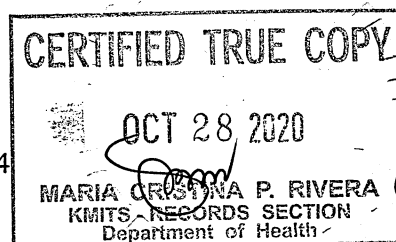
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V. GENERAL GUIDELINES

- 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

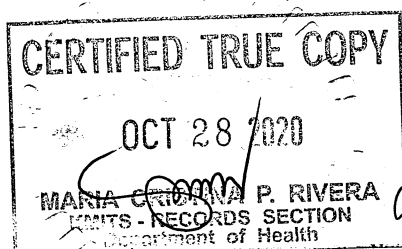
1. National Institutes of Health-Institute of Human Genetics (NIH-IHG) shall establish the CHGS of the Newborn Screening Program.
2. The NIH-IHG shall have administrative and operational oversight of all CHGS.
3. The NIH-IHG shall serve as the CHGS for Luzon. It shall establish satellite CHGS in Visayas, 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:

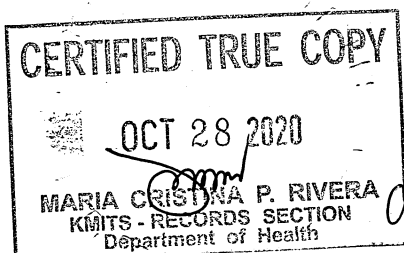
- a. Include the full coverage of the ENBS in the PhilHealth Newborn Care Package.
- b. Issue circulars defining the new policies and procedures on the enhancement of the Newborn Care Package, particularly on ENBS.
- c. Revise the coverage of the current Newborn Care Package based on the recommendations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



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6. NIH-IHG shall:

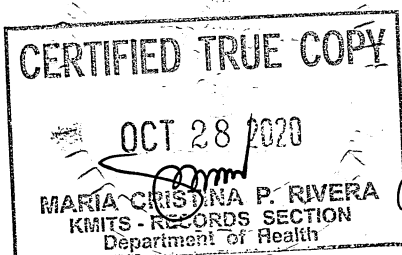
- a. Establish and oversee the operations of CHGS;
- b. Facilitate the procurement and distribution of goods needed by the NSCs and the CHGS;
- c. Submit to NSRC the annual funding proposal for the procurement and distribution of specific goods needed and the operations of CHGS; and
- d. Submit quarterly 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, NSF's, 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.

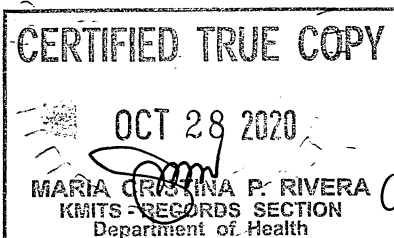
9. Newborn Screening Continuity Clinics (NBSCCs) shall:

- 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)

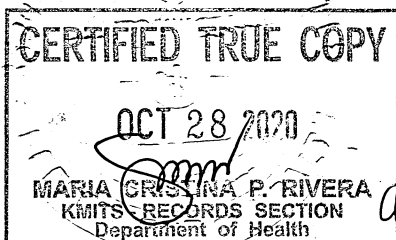


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- iii. 3rd offense - Administrative fine of one hundred thousand pesos (P100, 000)

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.

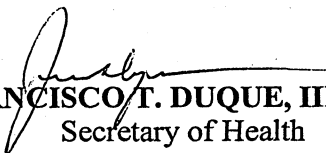
Operational details of the CHGS operations and Treatment Fund shall be incorporated in the MOA, Department Circulars, and/or Manual of Operations.

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

