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(In substitution of S. B. Nos. 1209 and 1372)

Prepared jointly by the Committees on Health and Demography, and Finance with Senators Defensor Santiago, Legarda, and Pia Cayetano as authors thereof

## AN ACT

ESTABLISHING A UNIVERSAL NEWBORN HEARING SCREENING PROGRAM FOR THE PREVENTION, EARLY DIAGNOSIS AND INTERVENTION OF HEARING LOSS AMONG CHILDREN

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

**SECTION 1.** *Short Title.* -This Act shall be known as the "Universal Newborn Hearing Screening and Intervention Act of 2008".

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, full and healthy development as individuals, and a better quality of life. The prevention, early detection and diagnosis of congenital hearing loss and interventions thereto should be based on applied research and the recognition that newborns and children who are deaf or hard-of-hearing have unique language, learning and communication needs, and should be the result of consultation with the sectors concerned.

SEC. 3. *Purpose.* -The purpose of this Act is to establish a Universal Newborn Hearing Screening Program (UNHSP) to institutionalize measures for the prevention and early diagnosis of congenital hearing loss among newborns and the provision of referral, early intervention, counseling and other support services for newborns with hearing loss, and their families, to afford them all the opportunities to be productive members of the community. The objectives of the UNHSP are:

- a. To ensure that all newborns have access to hearing loss screening;
- b. To institute a system of newborn hearing loss screening, follow-up, referral and recall for purpose of providing access to information and services on prevention of

1	hearing loss, early diagnosis and intervention, including consultations, to newborns
2	and their families:

- c. To establish a network among pertinent government and private sector stakeholders for the implementation, monitoring, evaluation and policy development to further universal newborn hearing screening program in the country;
- d. To provide continuing capacity building of stakeholders including training to practitioners, conduct of applied research, and other such activities to aid in the effective implementation of a universal newborn hearing screening program; and
- e. To establish and maintain a newborn hearing screening database.

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SEC. 4. *Definition of Terms*. –Under this Act, the following terms shall mean the following:

- a. "Universal Newborn Hearing Screening Program" or "UNHSP" shall refer to the program developed for carrying out hearing screening for all babies born in the Philippines and for providing adequate interventions for babies with congenital hearing loss;
- b. "Congenital hearing loss" shall refer to hearing loss present at birth;
- c. "Newborn hearing screening database" shall refer to an organized body of information related to newborn hearing screening;
- d. "Newborn" shall refer to a child from the time of complete delivery to thirty (30) days old;
- e. "Follow-up" shall refer to the monitoring of a newborn with possible hearing loss for purpose of ensuring that the newborn patient receives additional diagnostic services and intervention or treatment;
- f. "Recall" shall refer to a procedure for locating a newborn with a possible hearing loss for purposes of providing diagnostic services to confirm hearing condition and, as appropriate, provide intervention or treatment;
- g. "Newborn Screening Reference Center" shall refer 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 Universal Newborn Hearing Screening Program;
- h. "Newborn Hearing Screening Center" shall refer to a facility equipped with a newborn hearing loss screening and audiologic diagnostic evaluation laboratory that

- complies with the standards established by the NIH and provides all required laboratory tests and recall and follow-up programs for newborns with hearing loss;
- i. "NIH" shall refer to the National Institutes of Health;
- j. "Health Institutions" shall refer to hospitals, health infirmaries, health centers, lyingin centers or puericulture centers with obstetrical and pediatric services, whether public or private;
- k. "Newborn hearing loss screening" shall refer to an objective, physiological procedure completed in a child thirty (30) days old or below to determine the likelihood of hearing loss;
- "Audiologic diagnostic evaluation" shall refer to a service related to diagnosis of hearing loss as provided by professionals or centers certified by the NIH, through the DOH;
- m. "Advisory Committee" shall refer to the Advisory Committee on Newborn Hearing Screening established under Section 11 of this Act;
- n. "DOH" shall refer to the Department of Health;
- o. "Intervention" shall refer to any act to render service for a child diagnosed with hearing loss ranging from counseling, diagnosis, hearing aid or any medical procedure for correction of hearing loss; and
- p. "Referral" shall refer to an act of sending a patient to another service provider within the network for continuation of care.

SEC. 5. Obligation to Inform. -Any health practitioner who delivers, or assists in the delivery, of a newborn in the Philippines shall, prior to delivery, inform the parents or legal guardian of the newborn of the availability, nature and benefits of hearing loss screening among newborns or children three months old and below.

Parents or legal guardians of newborns who, after undergoing newborn hearing loss screening, have been found to have congenital hearing loss shall be informed of the availability, nature and benefits of diagnostic audiologic evaluation, intervention and treatment options, and counseling regarding hearing loss.

The DOH shall coordinate with the Advisory Committee to ensure the preparation and production of informational and educational materials for these purposes and ensure the distribution of the same in coordination with public and private health facilities, hospitals and local government units.

SEC. 6. Obligation to perform Newborn Hearing Loss Screening and Audiologic Diagnostic Evaluation. - Upon consent of parents or legal guardians, all babies born in hospitals in the Philippines shall be made to undergo newborn hearing loss screening before discharge, unless the parents or legal guardians of the newborn object to the screening subject to Section 7 of this Act. Babies who are not born in hospitals should be screened within the first three (3) months of life.

In the event of a positive newborn hearing loss screening result, the newborn shall undergo audiologic diagnostic evaluation in a timely manner to allow appropriate follow-up, recall and referral for intervention before the age of six (6) months; *Provided* That, audiologic diagnostic evaluation shall be performed by Newborn Hearing Screening Centers duly certified by the NIH.

It shall be the joint responsibility of the parents or legal guardian, and the practitioner or other person delivering the newborn to ensure that hearing screening is performed. An appropriate informational brochure for parents to assist in fulfilling this responsibility shall be made available by the DOH, through the Advisory Committee, and shall be distributed to all health institutions and made available to any health practitioner requesting it for appropriate distribution.

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SEC. 7. Refusal to be Tested. -A parent or legal guardian may refuse hearing loss screening on the grounds of religious beliefs but shall acknowledge in writing that they have been informed of their responsibility to perform said screening and their understanding that refusal for testing places their newborn at risk for undiagnosed congenital hearing loss. A copy of this waiver shall be made part of the newborn's medical record and refusal shall be indicated in the national newborn hearing screening database.

- SEC. 8. Continuing Education, Re-education and Training Health Personnel. The DOH, with the assistance of the National Institute for Health and other concerned government agencies, professional associations and civil society organizations, shall:
  - a. conduct continuing information, education, re-education and training programs for health personnel on the rationale, benefits, and procedures of hearing loss screening; and

b. disseminate information materials on newborn screening at least annually to all health personnel involved in material and pediatric care.

SEC. 9. *Licensing*. -To ensure the timely provision of hearing loss screening to newborns, the DOH shall require health institutions to provide hearing loss screening services as a condition for licensure. The Advisory Committee shall recommend to the DOH Secretary the acceptable standards and technologies of such services.

SEC. 10. Lead Agency. – The DOH shall be the lead agency in implementing this Act. It shall coordinate with all stakeholders from every stage of human development and at all levels of society in order to achieve the objectives of this Act.

For purposes of achieving the objectives of this Act, the DOH shall:

- 1. Establish an Advisory Committee on Newborn Hearing Screening in the Department of Health;
- 2. Coordinate with the Department of the Interior and Local Government (DILG) and the local government units for implementation of the provisions of this Act; and
- Coordinate with the Advisory Committee and the NIH Newborn
   Screening Reference Center for the certification of Newborn Hearing
   Screening Centers and preparation of defined testing protocols and
   quality assurance programs.

- SEC. 11. The Advisory Committee. To ensure the effective implementation of this Act, the Advisory Committee on Newborn Hearing Screening is hereby created to facilitate inter-agency coordination and the cooperation of private sector and professional associations in policy development, technology development, enforcement monitoring, databanking and training. The Advisory Committee shall be made an integral part of the Office of the Secretary of the DOH. It shall be composed of the Secretary of the DOH as Chairperson; Director of the Philippine National Ear Institute as Vice-Chairperson and the following as members:
  - a. Philippine Medical Association;
  - b. Philippine Pediatric Society;
  - c. Philippine Society of Otorhinolaryngologist Head and Neck Surgery;

- d. Philippines Obstetrics Gynecologic Society;
  - e. Philippine Hospitals Association;
  - f. Department of Education;
    - g. Department of Interior and Local Government;
    - h. Association of Municipal Health Officers of the Philippines;
    - i. A duly organized association of audiologists in the Philippines;
    - j. A duly organized association of midwives in the Philippines; and
    - k. Two representatives from civil society organizations.

Sec. 12. Responsibilities of the Advisory Committee. -The Advisory Committee shall provide technical assistance in the formulation of operational policies, plans and programs:

- a. To develop the State's capacity to support newborn hearing loss screening, early diagnosis and intervention;
- b. To monitor the extent to which hearing loss screening and audiologic diagnostic evaluation are conducted in health institutions, and assist in the development of universal newborn hearing loss screening programs for hospitals and non-hospital sites;
- c. To collect data on early detection, diagnosis and intervention that can be used for applied research and policy development;
- d. To develop models which ensure effective screening, referral and linkage with appropriate diagnostic, medical and qualified early intervention services providers and programs within the community; and
- e. To periodically review and recommend the newborn hearing loss screening fees to be charged by Newborn Screening Centers and to review the report of the Newborn Screening Reference Center on the quality assurance of the hearing loss screening and recommend corrective measures as deemed necessary.

SEC. 13. Establishment of Newborn Hearing Screening Center. -Newborn Hearing Screening Centers shall be established to provide newborn hearing loss screening, audiologic diagnostic evaluation and recall, follow-up and referral programs to babies with hearing loss; *Provided*, That, such centers shall be established through a

certification by the NIH based on standards formulated in collaboration with the Advisory Committee and the DOH.

Newborn Screening Centers (NSC) established pursuant to Section 12, of Republic Act No. 9288, shall adopt and implement a program to develop its capacity to become Newborn Hearing Screening Centers. The DOH and the Advisory Committee shall develop incentives to encourage the establishment of Newborn Hearing Screening Centers other than those under the Newborn Screening Centers.

SEC. 14. Data Management and Applied Research. – All hospitals and Newborn Screening Centers shall periodically submit copies of the results of the screening tests to the NIH Newborn Screening Reference Center for consolidation of patient databases. The NIH Newborn Screening Reference Center shall maintain a national database of children tested and a separate registry for those found positive for hearing loss. It shall submit reports annually to the Advisory Committee and to the DOH on the status of and relevant health information derived from the database.

A plan for long-term outcome evaluation of hearing loss screening utilizing the case registries shall be developed within one (1) year of passage of this Act by the NIH in consultation with the Advisory Committee. Implementation of this plan shall become a responsibility of the Advisory Committee.

 SEC. 15. Newborn Screening Fees. - The Philippine Health Insurance Corporation (PHIC) shall include the cost of hearing loss screening in its newborn package. The screening fee shall be applied to, among others, testing costs, education, registry, follow-up and reasonable overhead expenses. For this purpose, the PHIC shall develop a program for the gradual coverage of hearing loss screening, audiologic diagnostic evaluation, and intervention services subject to actuarial and feasibility studies.

## SEC. 16. Authorization of Appropriations. -

a. Nationwide Newborn Hearing Loss Screening, Diagnosis and Intervention Networks. -For the purpose of carrying out this Act, there are hereby authorized to be appropriated to the DOH Fifteen Million Pesos (P15,000,000) for the current fiscal year, Thirty

Т		willion resos (r50,000,000) for the next fiscal year, and such sums as may be
2		necessary for each of the succeeding fiscal years.
3	b.	Technical Assistance, Data Management and Applied ResearchFor the purpose of
4		carrying our this Act, there are hereby authorized to be appropriated to the National
5		Institutes of Health-Philippine National Ear Institute Five Million Pesos (P5,000,000)
6		for the current fiscal year and Seven Million Pesos (P7,000,000) for the next fiscal
7		year.
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9	SE	C. 17. Implementing Rules Within thirty (30) days from the effectivity of this Act,
10	the DOH	, in collaboration with relevant government agencies and professional associations,
11	shall deve	elop the implementing rules and regulations necessary to effectively implement the
12	provision	s of this Act.
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14	SH	EC. 18. Repealing ClauseAll laws, decrees, executive orders, proclamations and
15	administr	ative regulations, or any parts thereof, contrary to or inconsistent with this Act are
16	hereby re	pealed or modified accordingly.
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18	SI	EC. 19. SeparabilityIf any provision of this Act shall be held unconstitutional or
19		ne other provisions hereof shall remain valid and continue to be in full force and effect.
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21	SI	EC. 20. Effectivity This Act shall take effect fifteen (15) days after its publication in at
22	least two	(2) newspapers of general circulation.
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