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 1
GENERAL PROVISIONS

SECTION 1. *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
DEFINITION OF TERMS

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

1) Comprehensive 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 or 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 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 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 maternal 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 the Advisory Committee on Newborn Screening;

2) Develop the 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 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 an 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; and (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 three-(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 be 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 relating to newborn screening standards and practices, and shall provide technical assistance to newborn screening centers needing such assistance.

SEC. 15. *Database.* - All Newborn Screening Centers shall coordinate with the NIH Newborn Screening Reference Center for consolidation of patient databases. The NIH Newborn Screening Reference Center shall maintain a national database of patients tested and a registry for each condition. It shall submit reports annually to the 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 newborn screening utilizing the cases registries shall be developed within one (1) year of passage of this Act by the NIH Newborn Screening Reference Center in consultation with the Advisory Committee on Newborn Screening. Implementation of this plan shall become a responsibility of the Advisory Committee on Newborn Screening.

SEC. 16. *Newborn Screening Fees.* – The PHIC shall include cost of newborn screening in its benefits package. The newborn screening fee shall be applied to, among others, testing costs, education, sample transport, follow-up and reasonable overhead expenses.

To ensure sustainability of the National System for Newborn Screening, the newborn screening fee shall be divided and set aside for the following purposes: at least four percent (4%) to the DOH's Centers for Health Development or its future equivalent to be spent solely for follow-up services, education and other activities directly related to the provision of newborn screening services; at least four percent (4%) to the Newborn Screening Centers for human resource development and equipment maintenance and upgrading; at least four percent (4%) to the NIH Newborn Screening Reference Center for overall supervision, training and continuing education, maintenance of national database, quality assurance program and monitoring of the national program; and the balance for the operational and other expenses of the Newborn Screening Center.

ARTICLE 5
FINAL PROVISIONS

SEC. 17. *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. 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 circulation.

Approved,

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 Representatives 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: APR 0 7 2004

GLORIA MACAPAGAL-ARROYO
President of the Philippines

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