

[REPUBLIC ACT NO. 9288, April 07, 2004]

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 nongovernmental 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