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to provide a sustainable newborn screening system within the public health delivery system;

WHEREAS it is expedient to provide a comprehensive and coordinated interdisciplinary program of early screening and follow-up care for newborns in the healthcare institutions.

It is hereby enacted as follows:-

1. Short title, extent and commencement: (1) This Act may be called the Federal Newborn Screening Act, 2019.

(2) It shall be applicable in Islamabad Capital Territory.

(3) It shall come into force at once

2. Definitions.— In this Act, unless there is anything repugnant in the subject or context. -

- a) "comprehensive newborn screening system" means a screening system which includes but 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 and medical confirmation of test results, drugs and medical or surgical management and dietary supplementation to address the heritable conditions and evaluation activities to assess long term outcome, patient compliance and quality assurance;
- b) "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 of dietary prescriptions;
- c) "healthcare institution" means a hospital, health infirmary, health center, lying-in center with obstetrical and pediatric service, whether public or private;
- d) "healthcare practitioner" means a physician, nurse, midwife, nursing aide and traditional birth attendant;
- e) "heritable condition" means the condition which results in mental retardation, physical deformity or death if left undetected and untreated and is usually inherited from the genes of either or both biological parents of the newborn;
- f) "newborn" means a child from the time of complete delivery to thirty days old;
- g) "newborn screening" means an infant examined by pediatrician, ophthalmologist, ear, nose and throat specialist and orthopedic surgeon to exclude congenital abnormalities and performing biochemical testing for determining whether newborn has a suspected heritable condition;

- h) "parent education" means the various means of providing parents or legal guardian's information about newborn screening;
- i) "recall" means a procedure for locating a newborn with a possible heritable condition for purposes of providing the newborn with appropriate laboratory to confirm the diagnosis and, as appropriate, provide treatment;
- j) "Treatment" means the provision of prompt, appropriate and adequate medicine, medical, and surgical management or dietary prescription to a newborn for the purpose of treating or mitigating the adverse health consequences of the heritable condition.

3. Informational and educational materials on newborn screening.— (1) Government shall, with assistance of other Government agencies, professional societies and non-governmental organizations, arrange the dissemination of objective and informational and educational materials on newborn screening, and may, by notification in the official gazette, publish such instructions, guidelines or policies as it deems necessary or appropriate, for the purposes of producing and distributing informational and educational materials.

(2) A health practitioner who delivers or assists in the delivery, of a newborn shall, prior to delivery, inform the parents or legal guardians of the newborn of the availability, nature and benefits of newborn screening.

4. Performance of newborn screening.— (1) Newborn screening shall be performed after twenty-four hours of life but not later than three days from complete delivery of the newborn.

(2) A newborn placed in intensive care to ensure his survival shall be exempted from the condition of three days but shall be tested by seven days of age and it shall be the joint responsibility of the parent(s) and the practitioner or other person delivering the newborn to ensure that newborn screening has been performed. An appropriate informational brochure for parents to assist in fulfilling this responsibility shall be made available.

5. Protocols, policies and procedures of health institution for inspection.— (1) The healthcare institution shall have protocols, policies, and procedures available for inspection which provide operational details of the facility of newborn hearing screening program including

- a) the staff training criteria;
- b) staff roles and responsibilities, including supervision of screening outcomes
- c) referral and follow-up procedures;
- d) Protocols for follow-up testing of babies who were discharged before receiving a hearing screening. Follow-up protocols may include return to the hospital for outpatient screening or referral to an audiologist.
- e) procedure for reporting screening results in each individual child's medical record;
- f) culturally and linguistically appropriate information for distribution to parents;
- g) documentation of final screening prior to discharge including -
 - i. screening outcome (pass or refer);