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PART-IV

PROVINCIAL ASSEMBLY OF SINDH NOTIFICATION KARACHI, THE 1ST NOVEMBER, 2013.

NO.PAS/Legis-B-21/2013- The Sindh Newborn Screening Bill, 2013 having been passed by the Provincial Assembly of Sindh on 23rd September, 2013 and assented to by the Governor of Sindh on 30th October, 2013 is hereby published as an Act of the Legislature of Sindh.

THE SINDH NEWBORN SCREENING ACT, 2013.

SINDH ACT NO. XLVIII OF 2013.

AN ACT

to establish and integrate a sustainable newborn screening system within the public health delivery system;

WHEREAS to establish and integrate a sustainable newborn screening system within the public health delivery system and to provide a description of recommended procedures to audiologists performing follow up hearing screening or audiological assessment of infants identified during universal newborn hearing screening. **Preamble.**

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AND WHEREAS it is expedient to provide a comprehensive and coordinated interdisciplinary program of early hearing screening and follow-up care for newborns identified as referring from the hearing screening process. The goal is to screen all newborns for hearing impairment in order to alleviate the adverse effects of hearing loss to speech and language development, academic performance, and cognitive development;

It is hereby enacted as follows:-

Short title and
commencement.

1. (1) This Act may be called the Sindh Newborn Screening Act, 2013.

(2) It shall come into force at once.

2. 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) "health institution" means a hospital, health infirmary, health center, lying-in center or puericulture 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. (1) Government shall, with assistance of National Institute of Child Health and 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,

Informational and educational materials on newborn screening.

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

Performance of newborn screening.

(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.

Protocols, policies and procedures of health institution for inspection.

5. (1) The health 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);
- (ii) if a child is discharged from the hospital in "refer" status, the discharge documents will include a referral for follow up hearing testing;
- (iii) if a child is discharged from the hospital in "refer" status, an appointment will either be scheduled for follow up hearing testing as a hospital outpatient or the mother will be given information and resource materials to make an appointment for follow-up hearing testing;
- (iv) the follow up appointment is to occur within thirty days of referral from hearing screening and diagnostic procedures to be completed not later than three months of age.

(2) Each health institution shall provide all newborns a hearing screening prior to discharge.

Refusal to be tested.

6. (1) A parent or legal guardian may refuse testing on the grounds of religious beliefs, but shall acknowledge in writing their understanding, such refusal, places the newborn at risk for undiagnosed heritable conditions.

(2) A copy of refusal documentation shall be made part of the newborn's medical record.

7. The Health Department, Government of Sindh shall require the health institutions to provide newborn screening services as a condition for licensure or accreditation.

Licensing and accreditation.

8. For the purpose of achieving the objectives of this Act, the Health Department shall –

Achieving the objectives of the Health Department.

- (i) establish the Advisory Committee on newborn screening;
- (ii) develop the implementing rules and regulations for the immediate implementation of a provincial newborn screening program within fifteen days from the enactment of this Act;
- (iii) Coordinate with the Local Government Department, for implementation of the newborn screening program.

9. (1) There shall be an Advisory Committee on newborn screening to ensure sustained inter-agency collaboration and made integral part of the Health Department.

Advisory Committee on newborn screening.

(2) The Committee shall review annually and recommend conditions to be included in the newborn screening panel of

disorders and shall review and recommend the newborn screening fee to be charged by newborn screening centers.

(3) The Committee shall consist of –

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|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| (i) | Secretary of Health | Chairperson |
| (ii) | Executive Director of the National Institute of Child Healthcare | Vice-Chairperson |
| (iii) | Secretary Local Government or his nominee not below the rank of an Additional Secretary | Member |
| (iv) | Director Social Welfare for Children | Member |
| (v) | A representative of Pakistan Medical Association Sindh | Member |
| (vi) | three persons from amongst the pediatricians, obstetricians, endocrinologists, family physicians, nurses or midwives, from public or private sector to be appointed by the Secretary Health. | Members |
| (vii) | Three eminent persons to be appointed by Government | Members |

(4) The Committee may co-opt any person as a member for any particular purpose, but such person, shall not have right of vote.

(5) An official member appointed by virtue of his office, shall cease to be the member on vacating such office.

(6) A non-official member, shall hold office for a period of three years from the date of his appointment and shall be eligible for re-appointment for such duration as the Government may determine.

(7) A non-official member may at any time, before the expiry of his term, resign from his office, or be removed from office without assigning any reason.

(8) Any person appointed on a casual vacancy in the office of non-official member, shall hold office for the unexpired portion of the term of such vacancy.

(9) The members shall receive such remuneration as may be determined by Government.

**Meetings of
the
Committee.**

10. (1) The meetings of the Committee shall be held once in a quarter and presided over by the Chairperson and in his absence, the members present shall elect from amongst themselves a member to preside the meeting.

(2) Half of the total membership of the Committee shall constitute a quorum for a meeting of the Committee.

(3) The decision of the Committee shall be taken by the majority of its members present and, in case of a tie, the member presiding a meeting shall have a casting vote.

(4) All orders, determination and decision of the Committee shall be taken in writing.

**Over-riding
effect.**

11. Notwithstanding anything contained in any other law, rules or regulations, for the time being in force, or any order, proclamation, the provisions of this Act shall have over-riding effect.

Rules.

12. Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

**Removal of
difficulty.**

13. If any difficulty arises in giving effect to any provision of this Act, Government may make such order not inconsistent with the provisions of this Act as may appear to it to be necessary for the purpose of removing such difficulty.

**BY ORDER OF THE MADAM ACTING SPEAKER
PROVINCIAL ASSEMBLY OF SINDH**

**G.M.UMAR FAROOQ
ACTING SECRETARY
PROVINCIAL ASSEMBLY OF SINDH**