

Enforcement Rules of Genetic Health Act

Attachment :

Annex I Items of health or pre-marital examination

Annex II Scope of medical grounds for the identification of pregnancy or childbirth which might lead to life-threatening or endanger physical or mental health

Annex III The scope of the relevant medical reasons in identifying potential abnormal development on fetus

Article 1 The rules are prescribed pursuant to Article 17 in the Genetic Health Act (hereinafter referred to as the Act).

Article 2 Items of the health or pre-marital examination referred to in Article 6 see Annex I

Article 3 The Necessity stated in section 1 of Article 6 means the following circumstances:

1. Persons suspected to have a genetic, infectious or psychiatric diseases with genetic effects.
2. Persons whose relative by blood within the fourth degree of kin is suspected suffering from hereditary genetic diseases .
3. Persons are suspected of having a disease that requires a health examination.

When encountering one of above cases, public health care institutions, private hospitals and clinics at all levels shall report to local competent authority.

Article 4 The fertility regulation service and guidance stated in section 1

of Article 7 refer to the provision of various contraceptive methods, equipment, medicines, ligation, and infertility diagnosis for men and women with reproductive capacity; however, the implementation of ligation shall follow the terms set in Article 10.

Article 5 The health care services and guidance for pre-pregnancy, prenatal, perinatal, post pregnancy stated in section 2 of Article 7 means providing examinations, delivery, nutrition and health guidance during pregnancy.

Article 6 The infant and toddler health services referred to section 3 of Article 7 of the Act mean the provision of health examinations, vaccinations, required diagnosis and treatments, nutrition and health guidance for infants under one year old and children over one year old before school-starting age.

Article 7 The examinations, services, guidance and education referred to Article 6 and 7 shall be carried out by public health care institutions, private hospitals and clinics at all levels.

Article 8 Public health care institutions, private hospitals and clinics at all levels shall carry out outpatient activities and make case records, and persuade persons who need to carry out health or

pre-marital check to get such examination, as well as persuade patient to receive treatment and fertility regulation guidance.

Public health care institutions, private hospitals and clinics at all levels, if necessary, shall conduct family visits and educational advocacy.

Article 9 (Delete)

Article 10 The scope for persons suspected to have genetic defects , infectious diseases or mental illness referred to in this Act is as follows:

1. Persons who will affect normal fetal development, such as pregnant women suffering from phenylketonuria or Rubella.
2. Persons who are suffering from severe mental retardation or schizophrenia and therefore incapable to take care of baby.
3. Persons who may transmit abnormal chromosomes or genes to future generations, such as patients suffering from Down syndrome or Huntington's disease.

Article 11 The scope of medical grounds of pregnancy or delivery may cause life threatening risk or detrimental to her physical or mental health referred to in this Act is described in Annex II.

Article 12 The scope of medical grounds regarding the risk of

teratogenesis present for the fetus by medical consideration referred to item 2 of section 1 of Article 9

Article 13 The scope of marriages prohibited by law referred to item 5, section 1 of Article 9 in this Act is prescribed pursuant to provisions of Article 983 of the Civil Code.

Article 13-1 Mental health or family life is likely to be affected due to pregnancy or childbirth referred to item 6, section 1 of Article 9, shall not be identified based on the reason of fetal gender differences.

Article 14 Cases set out in Article 10 to Article 13 shall be determined by the designated physician performing induced abortion or litigation in accordance with provisions.

Article 15 Except required medical treatments, induced abortion shall be practiced within twenty four weeks of pregnancy. induced abortion within 12 weeks pregnancy shall be implemented by induced abortion specialists in hospitals or clinics; for pregnancy more than 12 weeks; such abortion shall be implemented by induced abortion specialist in hospitals under the condition of hospitalization.

Article 16 The agency imposing fines set out in this Act are the

municipality and county (city) government.

Article 17 This set of Regulations is implemented on the day of
announcement.

Annex I Items of health or pre-marital examination

1. Personal basic information

Personal occupational history, spouse occupational history, history of long-term administration of special medicines, smoking history, drinking history, family history of genetic disease.

2. General health examination

Measurements of height, weight and vision, identification of dyschromatopsia, general medical and surgical health checkup, chest X-ray, blood tests, urine tests, past medical history, past experience of pregnancy, birth history and condition of childbirth.

3. Genetic disease examination

(1) Family disease history inquiry.

(2) Chromosomal, genetic, and biochemical tests.

4. Infectious disease examination

(1) General examination: including tuberculosis, syphilis, gonorrhea, hepatitis, herpes and other viral infections.

(2) Pregnancy check: in addition to general inspection, Rubella shall also be checked.
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5. Mental illness examination

(1) Clinical psychiatric examination.

(2) Psychological tests.

(3) Electroencephalography (EEG).

(4) Inspection of the hereditary mental illness, according to genetic disease inspection items.

Annex II Scope of medical grounds for the identification of pregnancy or childbirth which might lead to life-threatening or endanger physical or mental health

1. Obstetrics: such as rupture of uterus, uterine perforation, metrorrhagia, myomectomy or caesarean section at previous childbirth, pregnancy-induced hypertension, Old age (aged over 35 years), the prolific childbirth and so on.
2. Surgery, gynecology: such as bladder and vagina suture, kidney transplantation, urinary diversion.
3. Orthopedic: such as severe kyphosis(or scoliosis), etc..
4. Hematology: such as hemostatic disorders, hemoglobinopathy, gammopathy, blood clotting abnormalities.
5. Cardiology: such as heart failure or myocarditis, rheumatic heart disease, history of stroke, hypertension or cerebral hypertension and cerebral aneurysm.
6. Chest: such as tuberculosis (administering anti-TB drugs), severe asthma, bronchial dilatation, emphysema, recurrent spontaneous pneumothorax, cystic fibrosis.
7. Urology: such as acute and chronic glomerulonephritis, renal hypertension, polycystic kidney disease , pyelonephritis, any kidney disease lead to renal dysfunction, and solitary kidney.
8. Endocrinology: such as severe diabetes, pheochromocytoma, hyperfunction or hypofunction of adrenal, thyroid or parathyroid glands.
9. Gastroenterology: pregnancy induced jaundice, abnormal liver function, mesenteric thrombosis, ulcerative colitis, diaphragm (muscular) hernia.
10. Immunology: immune deficiency diseases, Rh isoimmunization, rheumatoid arthritis, systemic lupus erythematosus, nodular multiple arteritis.
11. Neurology: severe central nervous system lesions, multiple sclerosis, muscular dystrophy, grand mal epilepsy.
12. Congenital illnesses: such as Down syndrome, genetic disorders.
13. Oncology: leukemia, Hodgkin's disease, breast and other cancers.
14. Chronic diseases: systemic fungal infection, tertiary syphilis, brucellosis.

15. Psychiatry:

(1) Mind loss or debilitation caused by functional and organic mental illness or retardation evaluated by physicians

(2) Severe mental retardation caused by genetic disease.

16. ENT: such as otosclerosis.

Annex III The scope of the relevant medical reasons in identifying potential abnormal development on fetus .

1. On maternal body

- (1) Chemical factors: such as pregnant women taking thalidomide or PCBs.
- (2) Physical factors: receive excess radiation due to clinical treatment.
- (3) Biological factors: such as the Rubella virus, polio virus infection, etc..

2. On fetus

Fetal deformity by identified the following methods of prenatal diagnosis,.

(1) Amniocentesis

- (i) Biochemical examination of amniotic fluid to discover open neural tube defects and congenital metabolic disorders.
 - (ii) Amniotic fluid cell culture to identify chromosomal or genetic abnormalities, such as Down syndrome and mucopolysaccharidosis disease.
- (2) Ultrasound diagnostic technique: hydrocephalus, anencephaly, spina bifida, coccygeal tumor, gastroschisis.
- (3) Fetal endoscopy : the deformity on fetal appearance which is difficult to correct.
- (4) In utero Fetal blood sampling : such as hemoglobinopathy, hemophilia, in utero fetal infection.
- (5) Chorionic villus sampling: Sampling cells to identify chromosomal or genetic abnormalities such as Down syndrome, thalassemia major, mucopolysaccharidoses.