

# **The Pre- Natal Diagnostic Techniques (Regulation And Prevention Of Misuse) Amendment Act, 2002**

## **THE PRE- NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) AMENDMENT ACT, 2002**

ACT NO. 14 OF 2003 [ 17th January, 2003.]

An Act further to amend the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

BE it enacted by Parliament in the Fifty- third Year of the Republic of India as follows:-

### 1. Short title and commencement.-

(1) This Act may be called the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 .

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. Substitution of long title.- In the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994 ) (hereinafter referred to as the principal Act), for the long title, the following long title shall be substituted, namely:-" An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre- natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or cert in congenital malformations or sex- linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto."

3. Amendment of section 1.- In section 1 of the principal Act, in sub- section 1, for the words and brackets" the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse)", the words and brackets" the Pre- conception and Pre- natal Diagno tic Techniques (Prohibition of Sex Selection)" shall be substituted.

### 4. Amendment of section 2.- In section 2 of the principal Act,-

(i) after clause (b), the following clauses shall be inserted, namely:-' (ba)" conceptus" means any product of conception at any stage of development from fertilisation until birth including extra embryonic membranes as well as the embryo or foetus;

(bb) " embryo" means a developing human organism after fertilisation till the end of eight weeks (fifty- six days);

(bc) " foetus" means a human organism during the period of its development beginning on the fifty- seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;'

(ii) in clause (d), the following Explanation shall be added, namely:-' Explanation.- For the purposes of this clause," Genetic Clinic" includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;';

(iii) in clause (e), the following Explanation shall be added, namely:-' Explanation.- For the purposes of this clause," Genetic Laboratory" includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;';

(iv) for clause (g), the following clause shall be substituted, namely:-' (g)" medical geneticist" includes a person who possesses a degree or diploma in genetic science in the fields of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining-

(i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956 ); or

(ii) a post- graduate degree in biological sciences;';

(v) for clause (i), the following clause shall be substituted, namely:-' (i)" pre- natal diagnostic procedures" means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, embryo, blood or any other tissue or fluid of a man, or of a woman before or after conception, for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre- natal diagnostic tests for selection of sex before or after conception;';

(vi) for clause (k), the following clause shall be substituted, namely:-' (k)" pre- natal diagnostic test" means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue or fluid of a pregnant woman or conceptus conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex- linked diseases;';

(vii) after clause (n), the following clauses shall be inserted, namely:-' (o)" sex selection" includes any procedure, technique, test or administration or prescription or provision of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex;

(p) " sonologist or imaging specialist" means a person who possesses any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956 ) or who possesses a post- graduate qualification in ultrasonography or imaging techniques or radiology;

(q) " State Board" means a State Supervisory Board or a Union territory Supervisory Board constituted under section 16A;

(r) " State Government" in relation to Union territory with Legislature means the Administrator of that Union territory appointed by the President under article 239 of the Constitution.'

5. Amendment of section 3.- In section 3 of the principal Act, for clause (2), the following clause shall be substituted, namely:-' (2) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess the qualifications as may be prescribed."

6. Insertion of new sections 3A and 3B.- After section 3 of the principal Act, the following sections shall be inserted, namely:-' 3A. Prohibition of sex selection.- No person, including a specialist or a team of

specialists in the field of infertility, shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them.

3B. Prohibition of ultrasound machine, etc., to persons, laboratories, clinics, etc., not registered under the Act.- No person shall sell any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of the foetus to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act."

7. Amendment of section 4.- In section 4 of the principal Act, for clauses (3) and (4), the following clauses shall be substituted, namely:-" (3) no pre- natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied for reasons to be recorded in writing that any of the following conditions are fulfilled, namely:-

(i) age of the pregnant woman is above thirty- five years;

(ii) the pregnant woman has undergone two or more spontaneous abortions or foetal loss;

(iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;

(iv) the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as, spasticity or any other genetic disease;

(v) any other condition as may be specified by the Board: Provided that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of the provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography;

(4) no person including a relative or husband of the pregnant woman shall seek or encourage the conduct of any pre- natal diagnostic techniques on her except for the purposes specified in clause (2);

(5) no person including a relative or husband of a woman shall seek or encourage the conduct of any sex selection technique on her or him or both."

8. Amendment of section 5.- In section 5 of the principal Act, for sub- section (2), the following sub- section shall be substituted, namely:-" (2) No person including the person conducting pre- natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives or any other person the sex of the foetus by words, signs, or in any other manner."

9. Amendment of section 6.- In section 6 of the principal Act, after clause (b), the following clause shall be inserted, namely:-" (c) no person shall, by whatever means, cause or allow to be caused selection of sex before or after conception."

10. Amendment of section 7.- In section 7 of the principal Act,-

(i) in sub- section (2), for clause (c), the following clause shall be substituted, namely:-" (c) three members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Women and Child Development, Department of Legal Affairs or Legislative Department in the Ministry of Law and Justice, and Indian system of Medicine and Homoeopathy, ex officio;"

(ii) in clause (e), for sub- clause (ii), the following sub- clause shall be substituted, namely:-" (ii) eminent gynaecologist and obstetrician or expert of stri- roga or prasuti- tantra."

11. Amendment of section 14.- In section 14 of the principal Act, for clause (f), the following clause shall be substituted, namely:-" (f) has, in the opinion of the Central Government, been associated with the use or promotion of pre- natal diagnostic technique for determination of sex or with any sex selection technique."

12. Amendment of section 15.- In section 15 of the principal Act, the following proviso shall be inserted, namely:-" Provided that no member other than an ex officio member shall be appointed for more than two consecutive terms."

13. Substitution of new section for section 16.- For section 16 of the principal Act, the following section shall be substituted, namely:-" 16. Functions of the Board.- The Board shall have the following functions, namely:-

(i) to advise the Central Government on policy matters relating to use of pre- natal diagnostic techniques, sex selection techniques and against their misuse;

(ii) to review and monitor implementation of the Act and rules made thereunder and recommend to the Central Government changes in the said Act and rules;

(iii) to create public awareness against the practice of pre- conception sex selection and pre- natal determination of sex of foetus leading to female foeticide;

(iv) to lay down code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics;

(v) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure its proper and effective implementation;

(vi) any other functions as may be prescribed under the Act."

14. Insertion of new section 16A.- After section 16 of the principal Act, the following section shall be inserted, namely:-" 16A. Constitution of State Supervisory Board and Union territory Supervisory Board.- (1) Each State and Union territory having Legislature shall constitute a Board to be known as the State Supervisory Board or the Union territory Supervisory Board, as th case may be, which shall have the following functions:-

(i) to create public awareness against the practice of pre- conception sex selection and pre- natal determination of sex of the foetus leading to female foeticide in the State;

(ii) to review the activities of the Appropriate Authorities functioning in the State and recommend appropriate action against them;

(iii) to monitor the implementation of provisions of the Act and the rules and make suitable recommendations relating thereto, to the Board;

(iv) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and

(v) any other functions as may be prescribed under the Act.

(2) The State Board shall consist of,-

- (a) the Minister in charge of Health and Family Welfare in the State, who shall be the Chairperson, ex officio;
- (b) Secretary in charge of the Department of Health and Family Welfare who shall be the Vice- Chairperson, ex officio;
- (c) Secretaries or Commissioners in charge of Departments of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, ex officio, or their representatives;
- (d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, ex officio;
- (e) three women members of Legislative Assembly or Legislative Council;
- (f) ten members to be appointed by the State Government out of which two each shall be from the following categories,-

- (i) eminent social scientists and legal experts;
- (ii) eminent women activists from non- governmental organisations or otherwise;
- (iii) eminent gynaecologists and obstetricians or experts of stri- roga or prasuti- tantra;
- (iv) eminent paediatricians or medical geneticists;
- (v) eminent radiologists or sonologists;
- (g) an officer not below the rank of Joint Director in charge of Family Welfare, who shall be the Member Secretary, ex officio.

- (3) The State Board shall meet at least once in four months.
- (4) The term of office of a member, other than an ex officio member, shall be three years.
- (5) If a vacancy occurs in the office of any member other than an ex officio member, it shall be filled by making fresh appointment.
- (6) If a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council she shall cease to be a member of the State Board.
- (7) One- third of the total number of members of the State Board shall constitute the quorum.
- (8) The State Board may co- opt a member as and when required, provided that the number of co- opted members does not exceed one- third of the total strength of the State Board.
- (9) The co- opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations.
- (10) In respect of matters not specified in this section, the State Board shall follow procedures and conditions as are applicable to the Board."

15. Amendment of section 17.- In section 17 of the principal Act,-

- (i) in sub- section (3), for clause (a), the following clause shall be substituted, namely:-" (a) when appointed for the whole of the State or the Union territory, consisting of the following three members-

- (i) an officer of or above the rank of the Joint Director of Health and Family Welfare- Chairperson;
- (ii) an eminent woman representing women' s organisation; and
- (iii) an officer of Law Department of the State or the Union territory concerned: Provided that it shall be the duty of the State or the Union territory concerned to constitute multi- member State or Union territory level Appropriate Authority within three months of the coming into force of the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 : Provided further that any vacancy occurring therein shall be filled within three months of the occurrence.";
- (ii) in sub- section (4), after clause (d), the following clauses shall be inserted, namely:-" (e) to take appropriate legal action against the use of any sex selection technique by any person at any place, suo motu or brought to its notice and also to initiate independent investigations in such matter;
  - (f) to create public awareness against the practice of sex selection or pre- natal determination of sex;
  - (g) to supervise the implementation of the provisions of the Act and rules;
  - (h) to recommend to the Board and State Boards modifications required in the rules in accordance with changes in technology or social conditions;
  - (i) to take action on the recommendations of the Advisory Committee made after investigation of complaint for suspension or cancellation of registration.";
- (iii) for sub- section (7), the following sub- section shall be substituted, namely:-" (7) No person who has been associated with the use or promotion of pre- natal diagnostic techniques for determination of sex or sex selection shall be appointed as a member of the Advisory Committee."

16. Insertion of new section 17A.- After section 17 of the principal Act, the following section shall be inserted, namely:-" 17A. Powers of Appropriate Authorities.- The Appropriate Authority shall have the powers in respect of the following matters, namely:-

- (a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;
- (b) production of any document or material object relating to clause (a);
- (c) issuing search warrant for any place suspected to be indulging in sex selection techniques or pre- natal sex determination; and
- (d) any other matter which may be prescribed."

17. Amendment of section 18.- In section 18 of the principal Act, for sub- section 1, the following sub- section shall be substituted, namely:-" (1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex o foetus and sex selection, or render services to any of them, after the commencement of the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 unless such Centre, Laboratory or Clinic is duly registered under the Ac."

18. Substitution of new section for section 22.- For section 22 of the principal Act, the following section shall be substituted, namely:-' 22. Prohibition of advertisement relating to pre- conception and pre- natal determination of sex and punishment for contravention.- (1) No person, organisation, Genetic Counselling

Centre, Genetic Laboratory or Genetic Clinic including clinic, laboratory or centre having ultrasound machine or imaging machine or scanner or any other technology capable of undertaking determination of sex of the foetus or sex selection shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement, in any form, including internet, regarding facilities of pre- natal determination of sex or sex selection before conception available at such Centre, Laboratory, Clinic or at any other place.

(2) No person or organisation including Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding pre- natal determination or pre- conception selection of sex by any means whatsoever, scientific or otherwise.

(3) Any person who contravenes the provisions of sub- section (1) or sub- section (2) shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees. Explanation.- For the purposes of this section, "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall- painting, signal, light, sound, smoke or gas.'.

19. Amendment of section 23.- In section 23 of the principal Act, for sub- sections (2) and (3), the following sub- sections shall be substituted, namely:-" (2) The name of the registered medical practitioner shall be reported by the Appropriate Authority to the State Medical Council concerned for taking necessary action including suspension of the registration if the charges are framed by the court and till the case is disposed of and on conviction for removal of his name from the register of the Council for a period of five years for the first offence and permanently for the subsequent offence.

(3) Any person who seeks the aid of any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or ultrasound clinic or imaging clinic or of a medical geneticist, gynaecologist, sonologist or imaging specialist or registered medical practitioner or any other person for sex selection or for conducting pre- natal diagnostic techniques on any pregnant women for the purposes other than those specified in sub- section (2) of section 4, he shall, be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees for the first offence and for any subsequent offence with imprisonment which may extend to five years and with fine which may extend to one lakh rupees.

(4) For the removal of doubts, it is hereby provided that the provisions of sub- section (3) shall not apply to the woman who was compelled to undergo such diagnostic techniques or such selection."

20. Substitution of new section for section 24.- For section 24 of the principal Act, the following section shall be substituted, namely:-" 24. Presumption in the case of conduct of pre- natal diagnostic techniques.- Notwithstanding anything contained in the Indian Evidence Act, 1872 (1 of 1872 ), the court shall presume unless the contrary is proved that the pregnant woman was compelled by her husband or any other relative, as the case may be, to undergo pre- natal diagnostic technique for the purposes other than those specified in sub- section (2) of section 4 and such person shall be liable for abetment of offence under sub- section (3) of section 23 and shall be punishable for the offence specified under that section."

21. Amendment of section 28.- In section 28 of the principal Act, in sub- section 1, in clause (b), for the words " thirty days", the words " fifteen days" shall be substituted.

22. Amendment of section 30.- In section 30 of the principal Act, for sub- section 1, the following sub- section shall be substituted, namely:-" (1) If the Appropriate Authority has reason to believe that an

offence under this Act has been or is being committed at any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other place, such Authority or any officer authorised in its behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such Authority or officer considers necessary, such Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such Authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act."

23. Insertion of new section 31A.- After section 31 of the principal Act, the following section shall be inserted, namely:- " 31A. Removal of difficulties.- (1) If any difficulty arises in giving effect to the provisions of the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 , the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty: Provided that no order shall be made under this section after the expiry of a period of three years from the date of commencement of the Pre- natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 .

(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament."

24. Amendment of section 32.- In section 32 of the principal Act, in sub- section (2),-

(i) for clause (i), the following clauses shall be substituted, namely:- " (i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (2) of section 3;

(ia) the manner in which the person conducting ultrasonography on a pregnant woman shall keep record thereof in the clinic under the proviso to sub- section (3) of section 4;";

(ii) after clause (iv), the following clauses shall be inserted, namely:- " (iva) code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics to be laid down by the Central Supervisory Board under clause (iv) of section 16;

(ivb) the manner in which reports shall be furnished by the State and Union territory Supervisory Boards to the Board and the Central Government in respect of various activities undertaken in the State under the Act under clause (iv) of sub- section (1) of section 16A;

(ivc) empowering the Appropriate Authority in any other matter under clause (d) of section 17A;".

---- K. N. CHATURVEDI, Additional Secy. to the Govt. of India.