

**MAHARASHTRA REGULATION OF USE OF PRE-NATAL
DIAGNOSTIC TECHNIQUES ACT, 1988**

15 of 1988

[28th April, 1988]

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MAHARASHTRA REGULATION OF USE OF PRE-NATAL DIAGNOSTIC TECHNIQUES ACT, 1988

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An Act to provide for the regulation of the use of medical or scientific techniques of pre-natal diagnosis solely for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital anomalies or sex-linked disorders and or prevention of the misuse of these techniques for the purpose of pre-natal sex determination leading to female foeticide; and for matters connected therewith or incidental thereto. WHEREAS, it is expedient to regulate of the use of pre-natal diagnostic procedures like Amniocentesis or any other present or future techniques, solely for the purpose of detection of genetic or metabolic disorders or chromosomal abnormalities or certain congenital anomalies or sex-linked disorders and to prevent the misuse of such techniques for pre-natal sex determination leading to female foeticide; and to provide for matters connected therewith or incidental thereto; It is hereby enacted in the Thirty-ninth Year of the Republic of India as follows: -

CHAPTER 1

Preliminary.

1. Short title, extent and commencement. :-

(1) This Act may be called as the MAHARASHTRA REGULATION OF USE OF PRE-NATAL DIAGNOSTIC TECHNIQUES ACT, 1988

(2) It shall extend to the whole of the State of Maharashtra.

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

2. Definitions. :-

In this Act unless the context otherwise requires,-

- (a) "advertisement" means any notice, circular, label, wrapper, printed matter or other document on display and also includes any announcement or visible representation made with the help of light, sound, smoke, gas, cinematograph films or video tapes;
- (b) "Appropriate Authority" means the State Appropriate Authority constituted by the State Government under S.6 of the MAHARASHTRA REGULATION OF USE OF PRE-NATAL DIAGNOSTIC TECHNIQUES ACT, 1988;
- (c) "Genetic clinic" or "clinic" means a place registered under this Act for the purposes of carrying out the activities of a Genetic Counselling Center as well as a Genetic Laboratory;
- (d) "Genetic Counselling Center" or "center" means an Institute, Hospital, Nursing Home or any place by whatever name called registered under this Act for providing Genetic Counselling to patients and for performing obstetrical or gynaecological procedures such as foetoscopy, taking samples of amniotic fluid, Chorionic Villi, blood or any tissue of a pregnant female for being sent to Genetic clinic or laboratory for pre-natal diagnostic test;
- (e) "Genetic laboratory" or "laboratory" means a place registered under this Act which provides facility for carrying out the analysis or tests of samples received from Genetic Counselling Centers for pre-natal diagnostic test;
- (I) "Gynaecologist" means a person who has acquired a post-graduate qualification in Gynaecology after obtaining M.B.B.S. degree;
- (g) "Local Vigilance Committee" means a committee appointed under Section 16 ;
- (h) "Medical Geneticist" means a person who has acquired a degree or diploma or certificate in the Medical Geneticist in the field of pre-natal diagnostic techniques or has experience of at least two years of work in that field after obtaining any of the following degrees, namely:-
 - (i) M.B.B.S. or any other degree equivalent thereto;
 - (ii) M.Sc. or Ph.D. in Biological Sciences or any other degree

equivalent thereto.

(i) "pre-natal diagnostic procedures" means all gynaecological or obstetrical or medical procedures such as foetoscopy taking samples of amniotic fluid, Chorionic Villi, blood or any tissue of a pregnant female for being sent to genetic clinic or laboratory for pre-natal diagnostic test;

(j) "pre-natal diagnostic technique" includes all pre-natal diagnostic procedures and pre-natal diagnostic tests;

(k) "pre-natal diagnostic test" means any test or analysis of amniotic fluid, Chorionic Villi, blood or any tissue of a pregnant female carried out in a Genetic clinic or laboratory in order to detect genetic or metabolic disorders or chromosomal abnormalities or certain congenital anomalies or haemoglobinopathies or sex-linked diseases;

(l) "prescribed" means prescribed by rules made under this Act;

(m) "registered medical practitioner" means a medical practitioner who possess any registered medical qualification as defined in clause (h) of Section 2 of the Indian Medical Council Act, 1956, and whose name has been entered in the register prepared or deemed to be prepared and maintained under the Maharashtra Medical Council Act, 1965 ;

(n) "State Vigilance Committee" means the Committee appointed by the State Government under Section 13 ;

(o) "Voluntary Organisation" means any Voluntary Organisation working in the field of Health or Women Welfare or Human Rights.

CHAPTER 2

Regulation of Center, Laboratory, Clinic and Pre-Natal Diagnostic Procedure and Techniques.

3. Regulation of centers and clinics. :-

(1) No Genetic center, laboratory or clinic, or place, unless registered Regulation techniques, under this Act shall carry out or associate or help in carrying out activities relating to the pre-natal diagnostic techniques with the help of procedures such as Amniocentesis, Chorionic Villi, Sampling or any other pre-natal diagnostic technique.

(2) No registered center, laboratory or clinic shall employ or take

services, whether honorary or on payment, from persons, including Gynaecologists, who do not possess the prescribed qualifications.

(3) No Medical Geneticist or Gynaecologist or medical practitioner or person shall carry out or help in carrying out or cause to carry out either himself or through his assistants, agents or associates, any pre-natal diagnostic technique at a place other than a Genetic Counselling Center, a Genetic clinic or a Genetic Laboratory registered under this Act.

4. Regulation of Pre-natal diagnostic procedure and techniques :-

(1) No place including the registered Genetic Counselling Center or Genetic clinic or Genetic Laboratory shall be used and no person shall use or cause to be used the pre-natal diagnostic techniques, except for the purposes specified in sub-sections (2) and (3).

(2) The pre- natal diagnostic technique shall not be used or carried out unless the person qualified to do so is satisfied that any one or more of the following conditions are fulfilled in each case, namely:-

(i) age of the pregnant woman is above 35 years;

(ii) History of two or more abortions of foetal loss;

(iii) History of exposure to potentially teratogenic drugs, radiation, infection or hazardous chemicals;

(iv) family History of mental retardation or physical deformities such as spastic or deaf- mute child or any other genetic disease;

(v) any other condition as may be approved by the Appropriate Authority.

(3) The pre -natal diagnostic technique shall be carried out under this Act solely for the purpose of detection of any one or more of the following abnormalities, namely:-

(i) chromosomal abnormalities;

(ii) genetic metabolic diseases;

(iii) haemoglobinopathies;

(iv) sex-linked genetic diseases;

(v) congenital anomalies;

(vi) any other abnormalities or diseases as may be declared by the Appropriate Authority for the purpose of this sub-section.

(4) Before carrying out the pre-natal diagnostic procedures, the person qualified to do so shall obtain a written consent of the female patient in the prescribed form after all possible side-effects and after-effects of such procedures are clearly explained to her.

5. Prohibition of Pre-natal diagnostic techniques for certain purposes On and from the commencement of this Act, :-

(1) no Genetic Counselling Center, laboratory, clinic, Gynaecologist, medical practitioner or any other person shall use or allow to be used the pre-natal diagnostic techniques including ultra-sonography for the purpose of indicating the sex of a foetus with or without the possible object of female foeticide.

(2) No center, laboratory or clinic shall give advertisement in any manner regarding facilities of pre-natal prediction of sex available at the center, laboratory or clinic.

(3) No person or members of family of a pregnant female shall seek to get the pre-natal diagnostic: procedure done for a purpose other than those mentioned in sub-section (3) of section 4.

CHAPTER 3

State Appropriation Authority

6. Constitution of State Appropriate Authority. :-

(1) On the commencement of this Act, or as soon thereafter as may be, the appropriate State Government may, by notification in the Official Gazette, constitute a State Appropriate Authority which shall consist of the following members, namely:-

(i) the Director of Health Services, ex-officio Chairman;

(ii) the Joint Director of Health Services, ex-officio Secretary;

(iii) two representatives of Voluntary Organisations;

(iv) the Director of Medical Education and Research or his representative, not below the rank of a Deputy Director;

(v) a Gynaecologist;

(vi) a Medical Geneticist;

(vii) a representative of the Indian Council of Medical Research. The

members referred to in clauses (ii), (iii), (v), (vi) and (vii) shall be nominated by the State Government.

(2) The Appropriate Authority may invite for its meeting the Civil Surgeon or Chief Medical Officer of the local area concerned as an Invitee-Member whenever it thinks necessary.

7. Meeting of Authority. :-

(1) The Appropriate Authority shall meet as and when necessary but not less than two meetings of the committee shall be held every year. The Appropriate Authority may frame rules for conduct of its business.

(2) All decisions in the meetings of the Appropriate Authority shall taken by simple majority of members present at a meeting and the quorum for a meeting shall be of five members including the Chairman. The decisions of the Authority shall not be vitiated or held as invalid only on the ground of vacancy or absence of any member.

(3) Any vacancy in membership of the Authority on account of death, resignation or any other reason shall be filled expeditiously by the State Government and until the vacancy is of filled the remaining members shall continue to function as if no vacancy has fallen.

(4) The terms, conditions and duration of office of the non-official members shall be such as the State Government may, from time to time determine.

8. functions of Authority. :-

(1) The functions of the Appropriate Authority shall be as follows, namely:-

(i) to advise the Government on policy matters relating to use of pre-natal diagnostic techniques;

(ii) to recommend to Government changes necessary in the rules prescribed under the Act in keeping with progress in science, evolution of new procedures and techniques and in the light of experience of the implementation of the Act;

(iii) to consider all applications made to it under section "9 for grant, or Section 10 for renewal, of registration of centers, laboratories and clinics;

- (iv) to consider the complaints of breach of provisions of this Act and rules and to take action of suspension or cancellation of registration under Section 11 ;
- (v) to prescribe guidelines about standards to be maintained by the registered centers, laboratories and clinics;
- (vi) to supervise and monitor the performance of centers, laboratories and clinics;
- (vii) to evolve a code of conduct for the persons who own, manage or run the center, laboratory or clinic and for persons employed in such center, laboratory or clinic;
- (viii) to create public awareness against the practice of female foeticide which results in discrimination against women even from the pre-natal stage;
- (ix) generally to supervise the implementation of the Act and rules made thereunder;
- (x) to take such other action as the State Government may direct.

(2) In discharging its functions under this Act, the Appropriate Authority shall have all the powers of a Civil Court in respect of the following matters under the Code of Civil Procedure, 1908 in trying a suit:-

- (a) proof of facts by affidavit;
- (b) summoning and enforcing the attendance of any person, and examining him on oath or affirmation;
- (c) compelling the production of documents; and
- (d) issuing commissions for the examination of witnesses.

CHAPTER 4

Registration of Center, Laboratory or clinic

9. Registration of Pre-natal diagnostic Centers, Laboratories or clinics :-

(1) Every Genetic center, laboratory and clinic; engaged, either partly or exclusively, in pre-natal diagnostic techniques for any of the purposes mentioned in sub-section (3) of Section 4 of this Act shall apply for registration within sixty days from such date as the State Government may, by notification in the Official Gazette, appoint in this behalf, being a date of constitution of the

Appropriate Authority. Such application shall be made in such form and manner and shall be accompanied by such fees as may be prescribed.

(2) Subject to the provisions of Section 5 , any center, laboratory and clinic engaged, in pre-natal diagnostic techniques for any of the purposes mentioned in sub-section (3) of Section 4 on the date appointed under sub-section (1) shall cease to carry out any pre-natal diagnostic technique on expiry of six months from such date unless such center, laboratory and clinic has already made an application for registration and is so registered before that date under this Act.

(3) No person shall open a new genetic center, laboratory and clinic after the commencement of the Act unless it is duly registered under this Act.

10. Certificate of registration. :-

(1) The Appropriate Authority shall after holding an inquiry, if necessary, and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder, grant a certificate of registration, in the prescribed form to the center, laboratory and clinic, as the case may be.

(2) If the applicant does not does not comply with the requirements of this Act and the rules the Appropriate Authority may give reasonable time to the applicant to effect such compliance. If, after the inquiry, and giving an opportunity to the applicant of being heard. the Appropriate Authority is satisfied that the applicant has not complied with such requirements, it shall reject the application for registration after giving reasons therefor.

(3) Every certificate of registration shall be renewed in such manner and after such period and on payment of such fees as may be prescribed.

(4) The certificate of registration shall be displayed by the registered center, laboratory and clinic in some conspicuous place in its office or place of business.

11. Cancellation or suspension of registration. :-

The Appropriate Authority may suo motu. or shall, on receipt of recommendation from the State Vigilance Committee or a Local Vigilance Committee, issue a notice to the center, laboratory or

clinic to show cause why its registration should not be suspended or cancelled for the reasons mentioned in the notice. If, after giving a reasonable opportunity to the center, laboratory or clinic the Appropriate Authority is satisfied that there has been a breach of any of the provisions of this Act or rules, it may, without prejudice to any criminal action that it may take against such center, laboratory or clinic, cancel or suspend its registration for such period as it may think fit.

12. Appeal. :-

(1) The center, laboratory or clinic of which application for registration has been rejected or against which an order of suspension or cancellation of registration has been passed by the Appropriate Authority, may, within thirty days from the date of receipt of the order, file an appeal to the State Government in the prescribed manner. The order of the State Government on appeal shall be final.

(2) If no appeal against the order of the Appropriate Authority directing suspension or cancellation of registration has been filed or if the appeal so filed has been rejected by the State Government, the copy of the order of the Appropriate Authority shall be forwarded by the Appropriate Authority to the Maharashtra Medical Council for taking suitable action against the medical practitioner practicing in such center, laboratory or clinic and in respect of which such order has been passed.

CHAPTER 5

Vigilance Committees

13. State Vigilance Committees. :-

On the commencement of this Act, or as soon thereafter as may be, the State Government shall appoint a State Vigilance Committee which shall consist of-

- (i) Secretary of the Appropriate Authority as Chairman and Convener;
- (ii) Two representatives of Voluntary Organisations;
- (iii) the Director-General of Information and Public Relations or his representative;
- (iv) A Gynaecologist;
- (v) A Medical Geneticist;

(vi) a Civil Surgeon or Chief Medical Officer.

14. Functions of State Vigilance Committee. :-

The functions of the State Vigilance Committee shall be-

(a) to pay periodic and surprise visits to the centers, laboratories or clinics, with a view to check compliance of the provisions of this Act and the rules;

(a) to investigate complaints by members of public or other Institutions or in the Press about contravention of the provisions of this Act or the rules;

(c) to seize incriminating evidence or record for further administrative or legal action;

(d) to recommend to the Appropriate Authority, the cancellation or otherwise of registration of, or prosecution against a center, laboratory or clinic;

(e) to check and prevent operation of unauthorized centers, laboratories or clinics;

(f) to take such other action as the Appropriate Authority or the State Government may direct.

15. Meetings of State Vigilance Committee. :-

(1) The State Vigilance Committee shall hold meetings as and when necessary to conduct business which may be placed before it. The committee shall have powers to frame rules for conduct of its business.

(2) All decisions in the meeting of members of the State Vigilance Committee shall be taken by a simple majority of members present at the meeting. There shall be a quorum of four members including the Chairman for a meeting.

(3) The decisions or any actions of the State Vigilance Committee shall not be vitiated or held as invalid only on the ground of vacancy or absence of any member.

16. Local Vigilance Committee :-

(1) There shall be a local Vigilance Committee for any such local area as the Appropriate Authority may specify. A local Vigilance Committee may consist of the following members, namely:-

- (i) Deputy Director of Health Services of the Region, ex-officio Chairman and Convenor;
 - (ii) District Health Officer of the concerned District;
 - (iii) Civil Surgeon or Chief Medical Officer of the local area;
 - (iv) Any officer not below the rank of a Tahsilcler having the powers of an Executive Magistrate nominated by the Collector;
 - (v) a Gynaecologist;
 - (vi) a Medical Geneticist;
 - (vii) a representative of the Women's Organisations.
 - (viii) a representative of any Voluntary Organisation;
- (2) the non-official Members of the local Vigilance Committee shall be nominated by the Appropriate Authority.

17. Meeting and functions of Local Vigilance Committee :-

- (1) All decisions in the meeting of local Vigilance Committee shall taken by simple majority of members present at the meeting. Then: shall be a quorum of four members including the Chairman for a meeting.
- (2) The decision or any action of a local Vigilance Committee shall not be vitiated or held as invalid only on the ground of a vacancy of absence of any member.
- (3) All decisions or any actions taken by a local Vigilance Committee shall be reported by it to the State Vigilance Committee in such manner and at such intervals as may be prescribed.
- (4) The functions and powers of a local Vigilance Committee shall be the same as that of the State Vigilance Committee, which shall be discharged by it within its local area.

18. Duration of appointment of non-official Members and their allowances. :-

- (1) The non-official Members of the State Vigilance Committee and a local Vigilance Committee shall be appointed for a period of three years and after expiry of the period of appointment they shall be eligible for re-appointment.
- (2) The non-official Members of these Committees shall be entitled

to travelling, sitting and other allowances at such rates as the State Government may from time to time, determine.

CHAPTER 6

Offences and Penalties.

19. Offences and Penalty. :-

(1) Any Medical Geneticist, Gynaecologist, Registered Medical Practitioner or any person who owns a center, laboratory or clinic or is employed in a center, laboratory or clinic or who gives his services to or at such a center, laboratory or clinic, whether honorary or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder shall, on conviction, be punished with rigorous imprisonment for a term which may extend to three years and with fine which may extend to rupees live thousand: Provided that, in the case of every conviction the period of sentence shall not be less than one year and fine shall not be less than rupees one thousand: Provided further that, the name of the Gynaecologist or Registered Medical Practitioner who has been convicted by Court shall be reported by the Appropriate Authority to the Maharashtra Medical Council for taking suitable action including that of suspension of his name from the Register of Council for a period of two years for the first offence and for permanent removal for subsequent offence.

(2) Any person who seeks the aid of a center or laboratory or clinic or of a Medical Geneticist or a Gynaecologist or a Medical Practitioner for carrying out pre-natal diagnostic techniques on a pregnant female for any purpose other than those specified in sub-section (3) of Section 4 , shall, on conviction, be punished with rigorous imprisonment for a term which may extend to three years and with fine which may extend to rupees three thousand: Provided that, in the case of every conviction under this sub-section the period of sentence shall not be less than one year and fine shall not be less than rupees one thousand: Provided further that, the Court shall always presume, unless otherwise proved, that a woman who seeks such aid of pre-natal diagnostic procedures on her self has been compelled to do so by her husband or members of his family, who shall, on conviction, be liable to be punished for abetment of the offence under this sub-section for the same sentence and in that case the woman shall be liable to pay a fine of rupees fifty for each such offence.

(3) Whoever contravenes any of the provisions of this Act or any

rule or any direction issued thereunder, for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which may extend to three months or with fine which may extend to one thousand rupees or with both, and in the case of continuing contravention, with an additional fine which may extend to five hundred rupees for every day during which such contravention continues after conviction for the first such contravention.

20. Offences to be cognizable, etc. :-

Every offence punishable under sub-section (1) or (2) of Section 19 shall be cognizable, non-bail able and non-compoundable.

21. Power of court :-

(1) No Court shall take cognizance of any offence under this Act except on a complaint made by-

(a) the Appropriate Authority, State or local Vigilance Committee or any officer authorised in this behalf by the State Government or the Appropriate Authority or State or local Vigilance Committee.

(b) any person who has given notice of not less than sixty days. in the manner prescribed, to the Appropriate Authority, any Vigilance Committee or an officer authorised as aforesaid, of the alleged offence and of his intention to make a complaint to the Court. and no Court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(2) Where a complaint has been made under clause (b) of sub-section (1) the Court may, on demand by such person, direct the Authority or Vigilance Committee to make available the relevant records in its possession to that person:

Provided that, the Authority or Committee may refuse to make any such record available to such person if the same is. in its opinion, against the public interest.

(3) The Court may, for adequate and special reasons to be recorded in judgement, impose a sentence less than the minimum sentence that can be imposed under this Act.

CHAPTER 7

Miscellaneous

22. Maintenance of records. :-

(1) All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules shall be preserved for a period of two years of such period as may be prescribed: Provided that, if any criminal or other proceedings are instituted against any center, laboratory or clinic, the records and other documents of such center, laboratory or clinic shall be preserved till the final disposal of such proceedings.

(2) All such record shall at all reasonable times be made available for inspection to the members of the Appropriate Authority or members of the State or local Vigilance Committee or to any other person as may be authorised by the State Government in this behalf.

23. Power to seize records. :-

(1) If the Appropriate Authority or the State or local Vigilance Committee has reason to believe that any breach of the provisions of this Act has been committed at any center, laboratory or clinic. or that pre-natal diagnostic procedures or techniques records are used for prediction of sex, then the Chairman of the State or local Vigilance Committee or any other member duly authorised by the State Government, the Authority or the Committee shall have power to search the premises of such center, laboratory or clinic and to seize such records and documents as may be necessary, on granting a receipt of the same, and the records and documents so seized shall be retained by the Authority or the Committee for so long period as may be necessary in connection with any proceeding or for a prosecution under this Act.

(2) The provisions of the Code of Criminal Procedure, 1973, shall apply to the proceedings taken under sub-section (1) and the person taking such proceeding shall take the assistance of a police officer of the nearest police station, whenever necessary.

24. Protection of action taken in good faith. :-

No suit, prosecution or other legal proceedings shall lie against the State Government, the Appropriate Authority, the State or local Vigilance Committee or any person acting under their authority for anything which is in good faith done or intending to be done under this Act.

25. Exemptions. :-

The State Government may exempt a Genetic center, laboratory or clinic run by it or by any local authority from any or all of the

provisions of this Act on recommendation by the Appropriate Authority that such exemption is in public interest: Provided that, such exemption is not made as regards minimum qualifications of person, minimum equipment necessary, the standard to be maintained and the code of conduct of persons working at the Genetic clinic, laboratory or clinic.

26. Power to make rules :-

(1) The State Government may, subject to the conditions of previous publication in the Official Gazette, make rules for carrying out the purposes of this Act: Provided that, if the State Government is satisfied that circumstances exist which render it necessary to take immediate action, it may dispense with the previous publication of any rule to be made under this Act.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for-

(i) the minimum qualifications of the persons employed at a registered center or laboratory or clinic;

[ii] the form and manner of application for registration, records to be maintained, consent of a female patient to be obtained at registered center or laboratory or clinic:

(iii) minimum equipment necessary at the center or laboratory or clinic;

(iv) the standard to be maintained by the center or laboratory or clinic;

(v) the code of conduct of persons working at the center or laboratory or clinic;

(vi) the manner in which an appeal may be filed to the State Government against the order of refusal, cancellation or suspension of registration;

(vii) the duration of validity of registration, procedure of renewal of registration and fees to be charged for registration and renewal thereof;

(viii) manner of and intervals at which a local Vigilance Committee shall report its decisions to the State Vigilance Committee;

(ix) the records, charts, reports, and other documents to be

maintained in center, laboratory or clinic, period for which such records, and documents shall be maintained and preserved;

(x) any other matter that is required or may be prescribed under this Act.

(3) Every rule made under this section shall be laid as soon as may be after it is made before each House of the State Legislature while it is in session for a total period of thirty days, which may be comprised in one session or in two successive sessions, and if, before the expiry of the session in which it is so laid or the session immediately following both Houses agree in making modification in the rule or Houses agree that the rule should not be made, and notify such decision in the Official Gazette, the rule shall, from the date of publication of such notification, have effect only in such modified form or be of no effect, as the case may be, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done or omitted to be done under that rule.