The Maharashtra Regulation of use of Pre-natal Diagnostic Techniques Rules, 1988

No. SDT. 1088/CR-108. FW-3.- *Whereas under the proviso to subsection (1) of section 26 of the Maharashtra Regulation of use of Prenatal Diagnostic .Techniques Act, 1988 (Mah. XV of 1988) (hereinafter referred to as "the said Act"), the Government of Maharashtra is satisfied that circumstances exist, which render it necessary to make rules under sub-section (1) and (2) of section 26 of the said Act without previous publication;*

Now, therefore, in exercise of the powers conferred by section 26 of the said Act and all other powers enabling in that behalf, the Government of Maharashtra hereby makes the following rules, namely

1. Short title and Commencement. –

1) These rules may be called The Maharashtra Regulation of use of Pre-natal Diagnostic Techniques Rules, 1988.

2) They shall come into force with effect from the 10th June, 1988.

2. Definitions. –

1) In these rules, unless the context otherwise requires-

   a) "Act" means the Maharashtra Regulation of use of Prenatal Diagnostic Techniques Act, 1988;

   b) "Form" means a Form appended to these rules;

   c) "Local area" means the area within the limits of a Municipal Corporation established under the relevant law for the time being in force in the State of Maharashtra;

   d) "Schedule" means a Schedule appended to these rules;

   e) "Section" means section of the Act.

2) Words and expressions used in these rules but not defined shall have the meanings respectively assigned to them in the Act.

3. Minimum requirements. – Every Centre, Laboratory and Clinic applying for registration under the Act shall possess a place, minimum equipment, and shall engage services of staff with minimum qualifications specified in Schedule I.

4. Procedure for application. –

1) Every application for registration of a Centre, Laboratory or Clinic shall be made in the form specified in Schedule II. Every such application shall be addressed to the Chairman of the Appropriate Authority and a duplicate copy of such application shall be forwarded simultaneously to the Civil Surgeon or the Chief Medical Officer of the Local Area.

2) Every application for registration of a Centre or a Laboratory or a Clinic shall also be accompanied by an undertaking in the form given in Schedule III.

5. Application fee. –

1) Every application for registration under rule 5 shall be accompanied by an application fee as follows:

a) Rs. 1000 for Centre,

b) Rs. 2000 for Laboratory and

c) Rs. 3000 for Clinic.

The fee shall be paid either in cash or by a demand draft payable to the Secretary of the Appropriate Authority. An institution run by Government or local authority shall be exempt from the payment of application fee.

2) If the application for registration is rejected by the Appropriate Authority, then it shall refund half the amount of fees paid by the centre, laboratory or clinic along with the application.

6. Processing of application. – The Civil Surgeon or the Chief Medical Officer of the local area shall on receipt of the copy of the application, fix a date not later than 21 days from the date of receipt of the application for a visit to the place personally alongwith, Chairman of the local Vigilance committee and such other members of the Committee as are available for visiting the place, on the date fixed as above to verify the particulars given in the application and its accompanying statements. The Civil Surgeon or the Chief Medical Officer shall forward his report to the Chairman of the Appropriate Authority alongwith his recommendations within a period of 30 days from the date of receipt of the application.

7. Consideration of report by Authority. – The Secretary of the Appropriate Authority shall, on receipt of the report mentioned in rule 7 call a meeting of the Authority within a period of 30 days from the date of receipt of each report and place the application and recommendations before it for consideration.

8. Constitution of Sub-Committee. – In the case of an application for Registration of a Laboratory or a Clinic, the appropriate authority may, if it considers necessary, constitute a sub-committee of its members to inspect the laboratory or clinic and give its recommendations to the Appropriate Authority.

9. Registration. – The Appropriate Authority, if satisfied, may give its approval to the registration of the Centre or Laboratory or Clinic. If not satisfied, it may reject the application giving reasons therefor within a period of 15 days from the date of such consideration by the Appropriate Authority and in any case within a period of 90 days from the date of receipt of Application by the Chairman.

10. Registration for specific tests. – The State Appropriate Authority may grant registration to a Centre, Laboratory or Clinic only for performing one or few specific pre diagnostic procedure or tests and decide the minimum equipment and qualification of persons required for the limited purpose.

11. Certificate of Registration. – The Certificate of registration to a centre or laboratory or clinic shall be issued with the signature of the Chairman or Secretary of the Appropriate Authority. In the form specified in Schedule IV and shall be valid for a period of 5 years. It shall be renewable after 5 years subject to the same conditions and the procedure as applicable to the first application but the fee for renewal shall be half of that being changed for fresh registration.

12. Maintenance of records. – Every Centre shall maintain minimum record in the form specified in Schedule V and every laboratory and clinic shall maintain minimum record in the form specified in Schedule VI. They shall also maintain such other record as may be directed by Appropriate Authority from time to time.

13. Preservation of Record. – All the important record including the case papers, Laboratory results, Microscopic Pictures, Sonographic Plates or Slides, recommendation letters and consent forms shall be preserved properly by the Centre or Laboratory or Clinic for a minimum period of 2 years from the date of carrying out the pre-natal diagnostic technique. If there are any legal proceedings during such period then the record shall be preserved till the final disposal of the legal proceedings.

14. Facilities for Inspection. – Every applicant for registration of a Centre or Laboratory or Clinic shall afford reasonable facilities for inspection of the place and all his records to the Civil Surgeon or the Chief Medical Officer and to persons duly authorised by the State Government or by the Appropriate Authority or by the State or Local Vigilance Committee.

15. Contravention of Act or Rules. – The Chairman or the Secretary of the Appropriate Authority or Chairman of the State or Local Vigilance Committee or Members authorised by them or the Civil Surgeon or the Chief Medical Officer of the local area or any of these officers jointly may pay periodic or surprise visits with or without other members of the bodies to the registered Centres, Laboratories and Clinics. If during such visits it is found that any of the provisions of the Act or the rules are being contravened the officers shall immediately report the matter to the Chairman of the State or local Vigilance Committee who shall call a meeting of the Committee to consider the report and to recommend, if necessary, suspension or cancellation of registration of the Centre or Laboratory or Clinic to the Appropriate Authority.

16. Cancellation or Suspension of Registration. – The Appropriate Authority on receipt of such recommendation shall give a reasonable opportunity to the owner of the centre or laboratory or clinic of being heard and, shall, if not satisfied with the explanation, either cancel the registration or suspend the same for such period as it may think fit.

17. Appeal. – If the owner of the Centre or Laboratory or Clinic, feels aggrieved by the order made under rule 16, he may file an appeal to the State Government within a period of 60 days from the date of receipt of the order of the Appropriate Authority. The memorandum of appeal shall be accompanied by non-refundable fee of Rs. 250 in the form of Court fee stamps.

18. Condition for analysis. – No laboratory shall accept for analysis or test any case unless referred to by a centre.

19. Consent Letter. – Every centre or clinic shall be required to obtain a consent letter from the patient in the form prescribed in Schedule VII.

20. Condition for procedure. – No Gynaecologist and no person at a centre or a clinic shall do the pre- natal diagnostic procedure without first duly locating the fetus on an ultra sonography machine so as to prevent any damage to the foetus.

21. Reports. – Every Centre, Laboratory and Clinic shall submit periodic reports regarding the tests carried out by them to the Civil Surgeon or the Chief Medical Officer of the local area and shall forward its copy to the local Vigilance Committee in such manner as may be directed by the Appropriate Authority from time to time.

22. Reports by Vigilance Committee. – The State and Local Vigilance Committees shall submit to the Appropriate Authority quarterly reports on the work and inspections done by them as per directions of the Appropriate Authority.

23. Publication of Information. – The Appropriate Authority may publish the findings from the reports received by it alongwith a list of approved Centres and Laboratories and Clinics periodically for the information of public and for use by experts in the field.

Schedule I

(See rule 3)

Minimum requirements which a centre, laboratory or clinic should possess for its registration

A. Place. – An aseptic room of adequate dimensions with aseptic arrangements as in an operation theatre (preferably air-conditioned). An area of 50 sq. feet for the Centre and 100 sq. feet in the case of Laboratory and 150 sq. feet for a Clinic shall be considered as of adequate dimension.

B. Equipment. –

a) In respect of Centre and Clinic. –

1) The equipments and accessories necessary for carrying out clinical examination by a gynaecologist.

2) The equipment, accessories, material and other facilities required for operations envisaged in the Act.

3) An ultra-sonography machine for location of foetus and placenta prior to removal of amniotic fluid or Chorionic Villi Aspiration and for other tests approved b the Appropriate Authority.

4) Appropriate catheters for carrying out chorionic viii aspirations per vagina, or appropriate equipment for chronic villi biopsy to be carried out per abdomen or vagina.

5) A suitable foetoscopy with appropriate accessories for foetoscopy, foetal biopsy or foetal blood sampling shall be optional.

6) Appropriate sterile needles for amniocentesis or cordocentesis.

7) Equipment for dry and wet sterilisation.

b) In respect of laboratory and clinic. –

1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.

2) Photomicroscope with fluorescent source of light.

3) Inverted microscope.

4) Incubator and oven.

5) Carbon dioxide incubator or closed system with 5% CO_2 atmosphere.

6) Autoclave.

7) Refrigerator.

8) Water bath.

9) Centrifuge.

10) Electrophoresis apparatus.

11) Chromatography chamber.

12) Calorimeter or Elisa reader or Radioimmunoassay system (with gamma-counter) or fluorimeter for various biochemical tests.

13) Vortex mixer.

14) Magnetic strirrer.

15) PH meter.

16) A sensitive balance (preferably electronic) to have a sensitivity of 0.1 milligram.

C. Staff. –

a) In respect of centre and clinic. –

A Gynaecologist with an experience of at least 2 years in genetic counselling and in pre-natal diagnostic procedures and preferably having experience in the use of ultra-sonography.

b) In respect of laboratory and clinic. –

1) A medical geneticist.

2) A Laboratory Technician with B.Sc. degree in Biological Science.

Schedule II

[Rule 4 (1)]

Form of Application for Registration of a Genetic Centre, Laboratory or Clinic

1.	Name of the Applicant Address-	
2.	Qualifications with Year of passing Registration No.	
3.	Experience in-	
	a) Diagnostic Procedures. (Applicable in respect of centre and clinic.)	
	b) Pre-natal diagnostic techniques (Applicable in respect of laboratory and clinic).	
4.	Name of Place Full Address	
5.	Type of Institution	*Government Hospital/ *Municipal Hospital/ *Pub Hospital/ *private Hospital/ *Private Nursing Home/ *Private Clinic.
6.	Specific Pre-natal Diagnostic Techniques for which approval is sought for e.g. amniocentesis, Chorionic Villi aspiration, etc.	
7.	a) Space available for the Centre, laboratory or clinic (Give dimensions of each room separately).	
	b) Whether any part is air-conditioned.	
8.	Equipment available with the make and model of each equipment List to be attached on a separate sheet).	
9.	a) Facilities available in the laboratory and clinic for the following tests :- *1. Ultrasound. 2. Amniocentesis 3. Chronic Villi aspiration 4. Fetoscopy.	
	b) Facilities available in the laboratory and clinic for the following tests: 1. Chromosomal Analysis 2. Chorion Villus Sampling	

	3. DNA analysis 4. Metabolic Analysis	

10.	a) Name and qualifications, Registration No. and experience of person who will carry out the genetic procedures (Applicable in respect of centre and clinic) and persons in charge of laboratory (Applicable in respect of laboratory and clinic).	
	b) Name, Qualification and Registration No. and experience of person in- charge of centre, laboratory and clinic.	
	c) Name, Qualification, Registration No. and experience of Sonologist.	
11.	State whether the Centre, Laboratory or clinic qualifies for approval in terms of minimum requirements laid down in Schedule I and if not, reasons therefor.	
12.	Is the undertaking in Schedule III attached.	
13.	Are similar undertakings obtained from all members of staff and kept on office record?	

Signature of the owner/in-charge

* Strike out whichever is not applicable or necessary

Schedule III

[See rule 4(2)]

Form of undertaking to be given by the person in-charge of a centre, laboratory or clinic alongwith application and by the staff of persons giving services to the centre, laboratory or clinic to the person in charge of these institutions

1. Shri/Smt……. residing at…….. hereby undertake not to disclose any information which will indicate the sex of the foetus to the patient or to her relatives or to any other person.

2. I fully understand that if there is a breach of this undertaking I shall be liable for a penalty as provided in the Maharashtra Regulation of use of Pre-natal

Diagnostic Techniques Act, 1988.

*3. As a person in-charge of a Centre/Laboratory/Clinic, I hereby agree to take similar undertakings in writing from my staff or persons giving services to my Centre/Laboratory/Clinic and to keep them on my record and make them available for verification/inspection to any authorised person.
Qualifications.
Registration No.
Designation
Nature of work done in the Centre/Laboratory/Clinic.

Signature of the person.

Date:

*Note: Para 3 should be struck off from the undertakings of persons other than the person in-charge of the Centre or Laboratory or Clinic.

Schedule IV

(See rule 11)

Certificate of Registration

In exercise of the powers conferred by section 10 of the Maharashtra Regulation of use of Pre-natal Diagnostic Techniques Act, 1988, the State Appropriate Authority hereby grants registration to the Genetic Counselling Centre*/Laboratory*/Clinic for purposes of carrying out the Pre-natal Diagnostic Procedures*/Pre Diagnostic Tests*/Pre Diagnostic Techniques, as defined in the aforesaid Act for a period of five years ending on

This registration is granted subject to the provisions contained in the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate, before the expiry of the said period of five years.

1) Name and address of the place of Centre/Laboratory/Clinic.
2) Name of Applicant who has been granted registration.
3) Name of persons approved for performing pre-natal diagnostic techniques.
4) Registration No. allotted.

Date:

Chairman/Secretary,
State Appropriate Authority.

* Strike out whichever is not applicable or necessary.

Schedule V

(See rule 12)

Record to be maintained by the Genetic Counselling Centre

1.	Patient's Name	

2.	Age	
3.	Husband's/Father's name	
4.	Full Address with Tel. No. if any	

5.	Referred -by (Full name and Address of Doctor/s) Registration No. (s). (Referral note to the preserved carefully with case papers.)	
6.	a) Last menstrual Period. b) …….. weeks of pregnancy.	
7.	Genetic/Medical Disease present in the family (specify.) Basis of diagnosis- 1. Clinical. 2. Bio-Chemical. 3. Cyto-Genetic. 4. Other (e.g. Radiologic).	
8.	Indication for pre-natal diagnosis- A. Previous child/children with genetic disease, viz. 1. Chromosomal disorders. 2. Metabolic disorders. 3. Malformation (s). 4. Mental Retardation. 5. Hereditary hemolytic anaemia. 6. X linked disorder.	
	B. Advanced age (more than 35 years).	
	C. Mother/Father has genetic disease (specify).	
	D. Other (specify)	
9.	Procedure carried out arid the full name of Gynaecologist or Sonologist who performed it, his address, Registration No. Procedure.	Name

	1. Chorionic villi aspiration. 2. Amniocentesis. 3. Ultrasound. 4. Foetal biopsy/Foetal blood sampling.	

10.	Laboratory tests to be carried out 1. Chromosomal analysis. 2. Bio-chemical assay. 3. DNA analysis. 4. Other (specify).	
11.	Name and address of laboratory where sample sent for tests and the date.	
12.	Result of pre-natal diagnosis: If abnormal, basis of diagnosis.	Normal/Abnormal

The Results coveyed to …….. On……..

Date:

Place:

Name and signature of the
Gynaecologist
who carried out Procedure
(vide Serial No. 9).

Schedule VI

(See rule 12)

Serial No., Month Year

Record to be maintained by the Genetic Laboratory and Clinic

1.	Patient's Name	
2.	Age	
3.	Husband's/Father's name -	
4.	Full Address with telephone number.	
5.	Referred by (Full name and Address of Doctor/s) Registration No. (referral Note	

	to be preserved carefully with case papers)	

6.	If pre-natal diagnosis advised, or recommended, specify indications.- A. Previous child with 1. Chromosomal disorder. 2. Metabolic disorder 3. Mental Retardation. 4. Malformation/s (specify). 5. Hereditary Haemolytic Anaemia. 6. X-linked disorder.	
	B. Advanced Maternal Age.	
	C. Genetic disease in Mother! Father (specify).	
	D. Other (specify).	
7.	Obstetric Technique carried out. 1. Amniocentesis. 2. Chorionic Villi aspiration. 3. Other (specify).	
8.	Laboratory Tests carried out. 1. Chromosomal analysis. 2. Bio-chemical Assay (specify). 3. DNA analysis (specify).	
9.	Result of pre-natal diagnosis If abnormal, give details.	
	Results conveyed to …….. On……..	

Date:
Place:

Name and Signature of the

Medical Geneticist

Registration No.

Schedule-VII

(See rule 19)

I , …….. wife/ Daughter of …….. aged …… Years residing at present at ……. with permanent address as given below, do hereby state on solemn affirmation that I have been explained fully the probable side effects and the after effects. of the pre-natal diagnostic procedures. I wish to undergo the procedures in my interest viz. with a view to find out the possibility of deformity or disorder etc. in the child which I am likely to deliver.

I undertake that I shall not terminate the pregnancy if the diagnosis shows the possibility of a normal child with either male or female sex. I understand that sex of the foetus will not be disclosed to me.

I understand that breach of this undertaking will make me liable to penalty as prescribed in the Maharashtra Regulation of use of Pre-natal Diagnostic Techniques Act, 1988.

Full Name

Permanent address:

Date:

Signature

I have explained the contents of the above declaration to the patient in vernacular as she does not understand English.

Date

Signature of the
person in-charge of the clinic.

By order and in the name of the Governor of Maharashtra,

S.S. Anaokar
Deputy Secretary of Government.
