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

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

whereas under the proviso to sub-section (1) of section 26 of the Maharashtra Regulation of Use of Pre-Natal Diagnostic Techniques Act. 1988 (Mah. XV of

1988) (hereinafter referred to as "the said Act"), the Government of Maharashtra is satisfied that the circumstances exist which render it necessary to make rules under sub-sections (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 as 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 this Act unless the context otherwise requires,-

(a) "Act" means the Maharashtra Regulation of Use of MAHARASHTRA REGULATION OF USE OF PRE-NATAL DIAGNOSTIC TECHNIQUES ACT, 1988;

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

(c) "local area" means the area within the limits of the Municipal Corporation established under the relevant law for the time being in fofce in the State of Maharashtra ;

(d) "Schedule" means a Schedule appended to these rules:

(e) "section" means a 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 Center, Laboratory or Clinic applying for registration under this Act shall possess a place, minimum equipment and shall engage services of staff with minimum qualifications specified in Schedule I.

4. Procedure lor application. :-

(1) Every application for registration of a Center, Laboratory or Clinic shall be made on 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 Chief Medical Officer of the local area.

(2) Every application for registration of a Center, Laboratoiy or Clinic shall also be accompanied by an undertaking in the form given in Schedule II.

5. Application fee :-

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

(a) Rs. 1000 for Center,

(b) Rs. 2000 for Laboratoiy, and

(c) Rs. 3000 for Clinic.

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

6. Processing of application. :-
The Civil Surgeon or 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 along with 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 Chief Medical Officer of the local area shall forward his report to the Chairman of the Appropriate Authority along with 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 clays 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 subcommittee 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 Center, Laboratoiy or Clinic. If not satisfied, it may reject the application giving reasons therefor with in 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 Center, Laboratoiy or Clinic only for performing one or few specific pre-natal 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 center or laboratory or clinic shall be issued with the signature of the Chairman or Secretary of 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 charged 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 records. :-
All the important record including the case papers, Laboratoiy results. Microscopic Pictures, sonography Plates and Slides, recommendation letters and consent forms shall be preserved properly by the Center, Laboratoiy 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. Preservation of records. :-
Every applicant for registration of Center, Laboratoiy or Clinic shall afford reasonable facilities for inspection to the place and all his records to the Civil Surgeon or Chief Medical Officer and to persons duly authorised by the State Government or the Appropriate Authority or by the State or local Vigilance Committee.

15. . :-
Contravention of Act or Rules The Chairman or Secretary of Appropriate Authority of the State or local Vigilance Committee or Members authorised by them or the Civil Surgeon or Chief Medical Officer of the local area or any other these officers jointly may pay periodic or surprise visits with or without other members of the bodies to the registration centers, laboratories or clinics. If during such visits it is found that any of the provisions of this Act or the rule are being contravened the officer 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 recommend if necessary, suspension or cancellation of registration of the Center, 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 center, 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 center, 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 clinic shall do a pre-natal diagnostic procedure without first duly locating the foetus on an ultra-sonography machine so as to prevent any damage to the foetus.

21. Reports. :-
Every center, laboratory or clinic shall submit periodic reports regarding the tests carried out by them to the Civil Surgeon or 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 Committees. :-
The Slate and local Vigilance Cosmmittees 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 along with a list of approved centers and laboratories and Clinics periodically for the information of public and for use by experts in the fields.

SCHEDULE 1
Minimum requirements which a center, laboratory or clinic should possess for registration.

Schedule I

(See rule 3)

Minimum requirements which a center, laboratory or clinic should Possess for 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 a Laboratory and 150 sq. feet in the case of a Clinic shall be considered as of adequate dimension.

B. EQUIPMENT:

(a) In *respect of a centre and clinic-*

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

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

(3) any ultra sonography machine for location of foetus and placenta prior to removal

of amniotic
fluid, Chorionic Villi Aspiration and for other tests approved by the Appropriate Authority.

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

(5) A suitable foeloseopy 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 sterilization.

(b) *In respect of a laboratory and clinic-*

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

(2) Photomicroscopc with fluorescent source of light.

(3) Inverted microscope.

(4) Incubator and oven.

(5) Carbon di-oxide incubator or closed system with 5% committee atmosphere.

(6) Autoclave.

(7) Refrigerator.

(8) Water

bath.

(9) Centrifuge.

(10) Electrophoresisapparatus.

(11) Chromatography chamber.

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

(13) Vortex mixer.

(14) Magnetic stirrer.

(15) PH meter.

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

C. STAFF: -

(a) In *respect of a centre and clinic-*

A Gynaecologist with an experience of at least 2 years in Genetic councelling and in pre-natal diagnostic procedure and preferably having experience in the use of ultra-sonography. (b) *In respect of a laboratory and clinic-*

(1) a Medical Geneticist.
(2) Laboratory Technician with B.Sc. degree in Biological Science.

SCHEDULE 2
Form of application for registration of a Genetic clinic, laboratory or Clinic.

Schedule II

(See rule 4(1))]

Form of application for registration of a Genetic clinic, laboratory or Clinic.

1. Name of the applicant Address-

2.

Qualifications-

Year of passing
Registration No.

3. Experience in-

(a) Diagnostic

Procedures.

(Applicable in respect of center 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 / Private Hospital / Private Nursing Home / Private Clinic.

6. Specified Pre-Natal Diagnostic Techniques for which approval is sought for e.g. amniocentesis,
chorionic villi aspiration, etc.

7. (a) Space available for the center, 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 in a separate sheet.)

9.(a) Facilities available in the laboratory and clinic for techniques following tests:-

1. Ultrasound
2. Amniocentesis
3. Chorionic Villi Aspiration
4. Fetoscopy.

(c)Facilities available in the laboratory and clinic for

techniques following tests:-

1. Chromosomal analysis
2. Chorion Villus sampling
3. DNA analysis
4. Metabolie analysis

10. (a) Name and qualifications, Registration No. and experience of person who will cany out the genetic procedures (Applicable in respect of center and clinic) a n d persons in charge of laboratory (Applicable in respect of laboratory and clinic).

(b) Name and qualifications. Registration No. and

experience of person in charge of the center.

laboratory or clinic.

(c) Name and qualifications, Registration No. and experience of sonologist.

11. Stale whether the center, laboratory or clinic qualifies for approval in terms of minimum requirements laid clown 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.

SCHEDULE 3

Form of undertaking to be given by the person in-charge of a center, laboratory or clinic along with application and by the staff of persons giving services to the center, laboratory or clinic lo the person in-charge of these institutions.

Schedule III

[See rule 4(2)]

Form of undertaking to be given by the person in-charge of a center, laboratory or clinic along with application and by the staff of persons giving services to the center, laboratory or clinic lo 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 center, laboratory or clinic. I hereby agree to take similar undertakings in writing from my staff or persons giving services to may Center / 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 Center / Laboratory / Clinic.

Date

Signature of the person.

SCHEDULE 4
Certificate of registration

Schedule IV

(See rule 11)

Certificate of registration

In exercise of the powers conferred by section 10 of the Maharashtra Regulation of Use of

P r e - N a t a l Diagnostic Techniques Act, 1988, the

State Appropriate Authority hereby grants registration to the Genetic Counselling Center / Laboratory / Clinic for the purposes of carrying out the pre-natal diagnostic procedures / pre-natal diagnostic tests / pre-natal 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 expity of the said period of five years.

(1) Name and address of the place of Center / Laboratory / Clinic.

(2) Name of applicant who has been granted registration.

(3) Names of person approved for performing pre-natal diagnostic techniques.

(4)

Registration

No. allotted.

Date

Chairman/ Secretary

State Appropriate Authority

SCHEDULE 5

Record lo be maintained by the Genetic Counselling Center

Schedule V

(See rule 12)

Record lo be maintained by the Genetic Counselling Center

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 be 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. Cylo-Genetic

4. Other (e.g. Radiologic)

8. indication of pre-natal diagnostic-

A. Previous child/children with genetic disease, viz.

1. Chromosomal disorders

2. Metabolic disorders

3. Malformation (s)

4. Mental retardation

5. Hereditary hemolytic anemia

6. X linked disorder

B. Advanced age (more than 35 years).

C. Mother/ Father has genetic disease (specify)

D. Other (specify)

9. Procedures carried out and the full name of Gynaecologist or Sonologist who performed it. his address. Registration No.

Procedure	Names
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 analysis

3. DNA analysis

4. Other (specify)

11. Name and address of laboratory Normal / Abnormal

where sample sent for tests and the date.

12. Result of pre-natal diagnostic:

If abnormal. basis of diagnosis.

Date

Place

Name and signature of the Gynaecologist

who carried out procedure (vide Serial No.9)

SCHEDULE 6

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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 Tel. No. if any.

5. Referred by (Full name and address of Doctor/s)

Registration No (s)

(Referral note to be preserved carefully with case papers)

6. If pre-natal diagnostic advised, or recommended, specify indications-
A. Previous child with

1. Chromosomal disorder

2. Metabolic disorders

3. Mental retardation

4. Malformation (s) (specify)

5. Hereditary hemolytic anemia

6. X linked disorder

B. Advanced Maternal age

C. Genetic disease in Mother/ Father has (specify)

D. Other (specify)

7. Obstetric Techniques carried out

1. Amniocenlesis

2. Chorionic villi aspiration

3. Other (specify)

8. Laboratory tests carried out-

1. Chromosomal analysis

2. Bio-chemical analysis (specify)

3. DNA analysis(specify)

9. Result of pre-natal diagnostic Normal / Abnormal
If abnormal give details

10. results conveyed to _____ on_____

Date

Place

Name and signature of the Medical Genetist

Registration No.

SCHEDULE 7

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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. 1 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 show the possibility of a normal child with either male or female sex. I understand that the 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 Rules, 1988. Full Name

Permanent address: Date

Signature

1 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.