

Ministry of Health & Family Welfare Government of India



Standard Operating Guidelines for District Appropriate Authorities

PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994

Ministry of Health and Family Welfare, Government of India In Collaboration with United Nations Population Fund

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Ministry of Health and Family Welfare, Government of India In Collaboration with United Nations Population Fund



जगत प्रकाश नड्डा Jagat Prakash Nadda





स्वास्थ्य एवं परिवार कल्याण मंत्री भारत सरकार Minister of Health & Family Welfare Government of India



Message

एक कदम स्वच्छता की ओर

The Government is leaving no stone unturned for the cause of the girl child in particular, and women in general. Sincere and concerted efforts are being made to bring about a transformational shift in the way our society looks at the girl child.

- 2. The major flagship programme of the Government, **Beti Bachao**, **Beti Padhao**, is focussed on 100 gender critical districts and addresses the declining Child Sex Ratio (CSR) and related issues of women empowerment over a life-cycle continuum.
- 3. One of the key elements of 'Beti Bachao, Beti Padhao' Scheme includes enforcement of PC & PNDT Act, 1994 along with nation-wide awareness and advocacy campaign and multi-sectoral action in select 100 districts (low on CSR) in the first phase. There is a strong emphasis on changing the societal mindset through training, sensitization, awareness generation and community mobilization at the grassroots.
- 4. Consistent capacity-building of officials entrusted with the responsibility of undertaking implementation of the Act on the ground, is the cornerstone of effective implementation of any Act. The object behind the law is strengthened when it is understood and applied in its true spirit. Towards this end, the Health Ministry has supported several training and sensitization programmes for the PC & PNDT Act implementing officials, as well as, made provisions for such programmes to be supported under the National Health Mission budgets.
- 5. Experiences in the field have indicated that there is a need for better communication and role clarity for the Appropriate Authorities, who are the implementers of the Act.
- 6. Recognising the need for continued guidance to strengthen PCPNDT Act implementation, the Health ministry has developed these standard guidelines to operationalize the intent behind the law. I commend the efforts of the team involved in

developing these detailed guidelines, which will go a long way in curbing technology misuse and ensuring effective Act implementation, to contribute meaningfully to the cause of the girl child in India.

- 7. Beyond the statistic, an adverse sex ratio speaks of enduring nature of social norms such as those related to son preference. However, this unsettling statistic also points to the criticality of ethics in medical practice. In this regard, I am confident these standard operating guidelines for District Appropriate Authorities will facilitate curbing malpractice and illegal use of technology for sex selection.
- 8. My hearty appreciation and best wishes for the endeavour.

Date: 6.4.2016

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(Jagat Prakash Nadda)





भारत सरकार स्वास्थ्य एवं परिवार कल्याण विभाग स्वास्थ्य एवं परिवार कल्याण मंत्रालय Government of India Department of Health & Family Welfare Ministry of Health & Family Welfare

Foreword



The 2011 Census reported a Child Sex Ratio (CSR) of 918 girls per 1000 boys. In some states like Jammu and Kashmir, the figure is even more alarming as there are only 862 girls for every 1000 boys, coming down drastically from 941 per 1000 in 2001. Similarly, while the Child Sex Ratio in Punjab and Haryana have shown an improvement in 2011 from the last census (2001), the child Sex Ratio is still disturbingly low – 846 in Punjab and 834 in Haryana. Further, there is a declining trend in as many as 18 States and 3 Union Territories. The decline in National CSR

has been unabated since 1961. This negative trend points to the fact that the girl child is at higher risk than ever before.

To overcome the growing and grave problem of sex selection leading to pre-birth elimination of female foetuses by misusing a prenatal diagnostic techniques, the Pre-Conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (PC&PNDT Act) was enacted. Under the two-decade-old Act, a machinery has been created to ensure that there is no sex selection at Pre-conception stage or thereafter and there is no prenatal determination of sex of foetus leading to female foeticide.

The PC&PNDT Act has several deterrent legal provisions and procedures. However, it is effective implementation of the Act that can meaningfully address this steady decline in Child Sex Ratio. The Government of India and the State Governments are paying increasing attention to strengthen the implementation of the Act, by taking many steps to stop use of illegal sex determination.

The Supreme Court of India is also concerned about the declining Child Sex Ratio and the same may be seen from the recent orders for the effective implementation of PC&PNDT Act.

Till date, a total of 1435 machines have been sealed and seized for violations of the PC & PNDT Act. A Total of 2142 court cases have been filed by the concerned Appropriate Authorities and 304 convictions have so far been secured under the Act. Following conviction the medical licenses of 100 doctors have been suspended/ cancelled. However, a lot more still remains to be done.

The PNDT Cell at the Ministry of Health and Family Welfare has prepared a compendium of Standard Operating Guidelines (SOGs) and best practices. The SOGs are intended to provide clarity to the District Appropriate Authorities for effective implementation of PC&PNDT Act. These SOGs are an outcome of a broad participatory process involving numerous women welfare organizations and the District Appropriate Authorities, having rich experience of enforcement and prosecution. The experts at State and Central Level have contributed through their wealth of knowledge and expertise to the development of these SOGs and guidelines.

It is expected that copies of these guidelines will be made available to all the District Appropriate Authorities, who should go through these guidelines, as these which will help them in effective implementation of the Act. I earnestly hope that the guidelines will serve its intended purpose of saving the girl child.

(B P Sharma)



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Preface



Though the Sex Ratio in the country has improved from 933 in 2001 to 940 in 2011, the Child Sex Ratio has dipped from 927 in 2001 to 918 in 2011. The alarming decline in the Child Sex Ratio is a matter of serious concern. The well-entrenched conservative attitudes in the Indian society for the preference of son and the aversion for daughter are resulting in higher girl child mortality, female infanticide and female

foeticide. Easy availability of the sex determination tests and illegal abortion services are proving to be catalysts in the process.

In order to check female foeticide, the technique of pre-conception sex selection has been brought within the ambit of the Pre-Conception and Pre-Natal Diagnostic Techniques Act (PC&PNDT Act), 1994 (as amended in 2003), so as to pre-empt the use of such technologies that adversely affect the Sex Ratio. Stringent punishments are prescribed under the Act to serve as a deterrent for violations of the Act.

The Government of India is taking several concrete steps to prevent the practice of female foeticide through effective implementation of the PC&PNDT Act. At the district level, as per the PC&PNDT Act, the Appropriate Authority of the district has been empowered to implement the Act. The Appropriate Authorities are empowered with the powers of Civil Court for search, seizure and sealing the machines, equipment and records of the violators of law including sealing of premises and commissioning of witnesses. They are aided and advised by the Advisory Committee in the discharge of its functions. The Advisory Committee consists of three medical experts, a legal expert, a publicity expert and three social activists.

Further, the Central PNDT Cell, Central and State level Supervisory Boards, and the National Inspection and Monitoring Committee (NIMC) have been set up for effective implementation of the Act. The Government is rendering financial support to the States and UTs for operationalization of PNDT Cells in addition to the other efforts such as Capacity Building, Orientation and Sensitization Workshop, Information, Education and Communication campaigns and for strengthening structures for the implementation of the Act under the National Health Mission (NHM).

Combating and preventing female foeticide through implementation of PC&PNDT Act requires a legally sustainable approach by all the stakeholders with a clear sense of fair play and justice. Keeping this in mind, the PNDT Cell in the Ministry of Health and Family Welfare, has painstakingly compiled Protocols, Standard Operating Guidelines (SOGs), Best Practices and other relevant resource material. I hope that this Manual will serve as guide and reference book to all the Appropriate Authorities, Inspecting Officers, Prosecutors and others, who are part of this noble mission of saving the girl child.

I convey my deepest appreciation to the collaborative hard work of all those associated with the formulation of this valuable resource material.

(C. K. Mishra)





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Introduction



Gender bias and deep-rooted prejudice and discrimination against the girl child and preference of the male child have led to the misuse of technology for Gender Biased Sex Selection leading to demographic imbalance in the last two decades. The declining Child Sex Ratio in India is a major concern for all. The Census data indicate that the female ratio has been declining at an alarming rate and would lead to serious socio-cultural problem including violence and population imbalances. The Child Sex Ratio (CSR) for the age

group of 0-6 years as per the 2011 Census has declined to 918 girls as against 927 per thousand boys (Census 2001)

The issue of survival of the girl child is a critical one, especially in the conservative Indian Society. This therefore, needs systematic efforts in mobilizing the community.

In order to check female foeticide, the Pre-natal Diagnostic Techniques (Regulations and Prevention of Misuse) Act, 1994 was enacted and brought into execution from 1st January, 1996. During the course of implementation of the said Act, certain inadequacies and practical difficulties in the working of the Act came to the notice of the Government, At the same time, techniques have been developed to select the sex of the child before conception. These developments were also taken note of by the Supreme Court in this various orders. After detailed deliberations, the PNDT Act and rules were amended and the amended Act/ Rules came into force with effect from 14th February, 2003. To make the law more stringent, various other amendments in PC & PNDT Rules 1996 rules have also been notified from time to time.

The main purpose of the Act has been to ban the use of sex-selection techniques before or after conception as well as misuse of pre-natal diagnostic techniques for sex selective abortions, and to regulate such techniques.

I take immense pleasure in presenting this "Standard Operating Guidelines for District Appropriate Authorities", containing detailed guidelines for the Appropriate Authorities Registration, including Renewal and Rejection, Inspection of Facilities, Search and Seizure, decoy operation and responding and filing of complaints. The objective of this "Standard Operating Guidelines for District Appropriate Authorities" is to facilitate the Appropriate Authorities in the effective implementation of PC&PNDT Act in a more comprehensive way so that the authorities can exercise their full powers and responsibilities that this Act has entrusted them, and contribute to the effective implementation of the Act. A few templates for seizure and seal Panchnama, Show Cause Notice for cancellation /suspension of registration etc., and different advisories issued by Ministry of Health and Family Welfare have been enclosed for the convenience of the Appropriate Authorities. The basis of this compilation is the Maharashtra Standard Operating Procedures developed by Ms. Varsha Deshpande and others and the consistent efforts of the PNDT Cell at the Ministry. I would like to acknowledge the support of UNFPA for substantive technical assistance in developing and printing these Standard Operating Guidelines.

I am confident that this "Standard Operating Guidelines for District Appropriate Authorities" will help in the proper and effective implementation of the PC & PNDT Act. I also commend the painstaking effort of all those who are associated with this valuable compendium, for developing a rich reference book.

Rabe (Dr. Rakesh Kumar)

Acknowledgments

There was a long felt need for comprehensive guidelines for effective implementation of the PC and PNDT Act. These guidelines have now been put together by the Ministry of Health and Family Welfare along with the United Nations Population Fund. Extensive discussions were held by the PC PNDT Team of Ministry of Health and Family Welfare with the PNDT team of the Government of Maharashtra. The initiatives taken and mechanisms set up by Maharashtra and other states for effective implementation of the PCPNDT Act, together with thorough discussions with the Ministry of Health and Family Welfare officials and experts, have facilitated in detailing of the Act and the Rules in the form of these Standard Operating Guidelines(SOGs).

We express sincere gratitude to the Secretary, Health and Family Welfare, Shri Bhanu Pratap Sharma. This document has become a reality owing to his unflinching encouragement and support. Additional Secretary and Mission Director, Shri C.K. Mishra has been a constant beacon of inspiration and support to the entire team of PNDT and we wish to acknowledge the same for the present endeavour as well. The guidelines have been finalized under the overall guidance and supervision of Dr. Rakesh Kumar, Joint Secretary (RCH), Government of India.

SoGs have a sound backing in the main Act. Linking of the guidelines to the Act in the background of emerging queries from states, was guided by Ms. Bindu Sharma, Director, PNDT, Government of India. Critical inputs from Shri Manoj Jha, Under Secretary, PNDT as well as feedback from Shri Shashank Sahu, Section Officer, Shri Gurdeep, Senior Statistical Officer, Ms. Ifat Hamid, Consultant, PNDT are acknowledged. Inputs from Legal Consultants, PNDT, Shri Munish Tandon, along with Shri Sanjeev Narula, are noteworthy especially, the application of relevant provisions of Criminal Procedure Code as envisioned in the main Act.

These guidelines and their finalisation would not have been possible without the consistent technical assistance and support of UNFPA. In particular, extensive efforts of Dhanashri Brahme, Programme Specialist, Gender, are acknowledged in laboriously putting together the first draft and working on several revisions subsequently to give this document its final shape. Along with guidance from Ena Singh, Assistant Representative, UNFPA, substantive contributions of Anuja Gulati, UNFPA State Programme Coordinator for Maharashtra are also acknowledged, together with inputs from Shobhana Boyle, National Programme Officer. Rajat Ray, Vidya Krishnamurthy and Manpreet Kaur from the UNFPA team facilitated designing and printing of the document.

The efforts of Advocate Ms. Varsha Deshpande, Lek Ladaki Abhiyan, Dalit Mahila Vikas Mandal, Satara, Maharashtra are acknowledged in putting together the guidebook for Appropriate Authorities, which has formed the basis of these SoGs. Guidance and inputs of Government of Maharashtra PNDT cell officials Dr. A. Khade and Advocate S. Kulkarni are worth mentioning and are appreciated in informing the contents of these guidelines. Inputs of the Health Department officials from State Governments of Andhra Pradesh, Assam, Maharashtra, Odisha, Rajasthan are noteworthy in helping review the first draft of this document.

Tathapi Trust, Pune is acknowledged for the English translation of the original Appropriate Authority guidebook developed under the Lek Ladki Abhiyan and the translation of relevant Government of Maharashtra guidelines and resolutions.

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*Note: While an effort has been made to duly link each section of the standard operating guidelines with the provisions of the PCPNDT Act and Rules, it is advised that the content of these guidelines be read in conjunction with the details contained in the Bare Act to ensure a complete understanding of the law and its application. In the eventuality of any clarification, refer to the Bare Act.

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1. Code of Conduct for Appropriate Authorities under the PCPNDT ACT

G.S.R. 119(E).- In exercise of the powers conferred by section 32 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules further to amend the Preconception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, namely :-

- 1. These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2014.(2) They shall come into force on the date of their publication in the Official Gazette.
- 2. In the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, after rule 18, the following rule shall be inserted, namely:-



18-A Code of Conduct to be observed by Appropriate Authorities.-

(1) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following general code of conduct, namely:-

- maintain dignity, and integrity at all times
- observe and implement the provisions of the Act and rules in a balanced and standardised manner in the course of their work
- conduct their work in a just manner without any bias or a perceived presumption of guilt
- refrain from making any comments which demean individuals on the basis of gender, race, religion
- delegate his or her powers by administrative order to any authorised officer in his or her absence and preserve the order of authorisation as documentary proof for further action.



(2) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following Conduct for Advisory Committees, namely:

- ensure that the re-constitution, functions and other relevant matters related to advisory committee shall be in accordance with the provisions of the Advisory Committee Rules, 1996
- ensure that a person who is the part of investigating machinery in cases under the Preconception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994,(57 of 1994), shall not be nominated or appointed as a member of the Advisory Committee
- ensure that the process of filling up of vacancies in Advisory committee shall start at least ninety days before the probable date of the occurrence of vacancy

- ensure that no person shall participate as a member or a legal expert of the Advisory Committee if he or she has conflict of interest
- conduct frequent meetings of the Advisory Committee to expedite the decisions regarding renewal, cancellation and suspension of registration.



(3) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for processing of complaint and investigation, namely:

- maintain appropriate diaries in support of registration of each of the complaint or case under the Act
- attend to all complaints and maintain transparency in the follow-up action of the complaints
- investigate all the complaints within twenty four hours of receipt of the complaint and complete the investigation within forty-eight hours of receipt of such compliant
- as far as possible, not involve police for investigating cases under the Act as the cases under the Act are tried as complaint cases under the Code of Criminal Procedure, 1973 (2 of 1974).



(4) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for registration and renewal of applications under the Act, namely:

- dispose of the application for renewal and new registration within a period of seventy days from the date of receipt of application
- ensure that no application for fresh registration or renewal is accepted if any case is pending in any court against the applicant for violation of any provision of the Act and Rules made thereunder¹.



(5) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for Legal Action, namely:

- ensure that protection and expenses of witness shall be met from the registration amount collected
- ensure that all the notifications of the Government be produced in original in the court and a copy of the same be preserved
- ensure that while filing the cases, all the papers, records, statements, evidence, panchnama and other material objects attached to the case file shall be in original
- suspend the certificate of registration in the course of taking legal action of seizure and sealing of the facility

¹ Substituted by GSR 60 (E) dated 28 January 2015, for clause (ii), which before substitution stood as "...if any case is pending in any court against the applicant".

- ensure that there shall be no violation of the provisions of the Medical Termination Pregnancy Act, 1971 (34 of 1971) and the rules made there under while implementing the provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996
- take immediate action for filing appeal, revision or other proceeding in higher courts in case of order of acquittal within a period of thirty days but not later than fifteen days of receipt of the order of acquittal.

(6) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall submit quarterly progress report to the Government of India through State Government and maintain Form H for keeping the information of all the registrations made readily available.

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(7) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following regulation of ultrasound equipments, namely:

- monitor the sales and import of ultrasound machines including portable or buyback, assembled, gift, scrap or demo
- ensue regular quarterly reports from ultrasound manufacturers, dealers, wholesalers and retailers and any person dealing with the sales of ultrasound machines at the State level
- conduct periodical survey and audit of all the ultrasound machines sold and operating in the State or district to identify the unregistered machines
- file complaint against any owner of the unregistered ultrasound machine and against the seller of the unregistered ultrasound machine.



(8) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for inspection and monitoring, namely:

- conduct regular inspection of all the registered facilities once in every ninety days and shall preserve the inspection report as documentary evidence and a copy of the same be handed over to the owner of facility inspected and obtain acknowledgement in respect of the inspection
- place all the inspection reports once in three months before the Advisory Committee for follow up action
- maintain bimonthly progress report containing number of cases filed and persons convicted, registration made, suspended or cancelled, medical licenses cancelled, suspended, inspections conducted, Advisory Committee meetings held at the district level and quarterly progress report at the State level

- (a) procure the copy of the charges framed within seven days and in the case of doctors, the details of the charges framed shall be submitted within seven days of the receipt of copy of charges framed to the State Medical Council
 - (b) procure the certified copy of the order of conviction as soon as possible and in the case of conviction of the doctors, the certified copy of the order of conviction shall be submitted within seven days of the receipt of copy of the order of conviction.



(9) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for accountability, namely:

- obtain prior sanction or approval of the Government of India for any resolution concerning the implementation of the provisions of the Act
- take action, if any, required under the Act and immediately on receipt of notice under clause (b) of sub-section (1) of section 28 of the Act and if he or she fails to do so, shall not be entitled for the protection under section 31 of the said Act and defend the case in his or her own capacity and at his or her own cost.



(10) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall follow the following financial guidance, namely:

- maintain a separate and independent bank account operated by two officers jointly, at all levels
- ensure transparency and adhere to standard Government financial norms for disbursement of money.



2. About the Equipment Capable of Sex Selection

About the sale of equipment [Rule 3 A and 3B]

[State governments may issue circular/s supplementing the Act providing instructions to manufacturers]

- 1. Sale or use of Ultrasound machines at a place/centre not registered under this Act is prohibited by the law. Distributing, supplying, lending, renting, authorizing, handing over of any such machine to an unregistered centre/place under the Act is also prohibited [Section 3B and Rule 3A(1)]
- 2. Any person* that sells/provides machines is bound by law to send to the Appropriate Authority of the Centre/State every three months the list of buyers/recipients of ultrasound machines/equipments as well as the details of the machines sold/provided [Section 3A (2)]
- 3. Any person*buying such a machines is bound by the law to submit an affidavit undertaking that the said machine will not be used for sex determination or sex selection before or after conception[Section 3A (3)]
- 4. Manufacturer/dealer will submit its quarterly report of sales to the Appropriate Authority (even if it is a nil report)
- 5. Manufacturer/dealer to report to the SAA about old machines/equipment purchased or bought back from buyers/purchasers.

* Person includes association of persons, body of individuals and a company



About the use of portable machines

The use of portable ultrasound machines or any other portable machine or device which has the potential for selection of sex before conception or detection of sex during pregnancy, is permitted only in the following conditions: [Rule 3B]

- a) the portable machine being used, within the premises it is registered, for services to the indoor patients [Owner to specifically define 'premises' under Form A – annex 1. Diagram of the 'premises' and exact 'premise' where the machine will be used to be mentioned in Form B – annex 3]
- b) as a part of a mobile medical unit, offering a bouquet of other health services. Other health and medical services has been defined as the host of services provided by the mobile medical unit which may include curative/reproductive and child health services/family planning services/diagnostic/specialised facilities and services/ emergency services as per the Rule.



3. Guidelines Concerning the District Advisory Committee



When and how to seek advice from the district advisory committee? [GSR 540 (E), dated 26-11-1996]

- 1. The role of the Advisory Committee is critical for providing advice in the context of grant, renewal or rejection of registration [Section 19(1) (2) (3), Rule 6(2) (3), Rule 8 (2)] suspension and cancellation of registration [Section 17 (8)]
- The Committee has to discuss, provide advice approving or rejecting the new registration of a centre or renewal of registration, cancellation or suspension of registration [Rule 6(2)]
- An advisory committee shall meet at least once in every two months/sixty days [Rule 15]
- 4. At least seven clear days' notice of all meetings of advisory committee shall be given to each member, but an urgent meeting may be called at a shorter notice depending upon the urgency
- 5. The Advisory Committee will comprise of three medical experts from among gyneacologists, obstetricians, paediatricians and medical geneticists, one legal expert, one officer of IEC department of the State Government or the Union Territories as the case may be and 3 eminent social workers at least one of them representing a women's organisation [Section 17 (6)]
- 6. Each member shall hold office for a period not exceeding three years
- 7. One of the members of the Advisory Committee will be the Chairperson of the Committee (AA cannot be the Chairperson/member of the Committee) [Section 17 (5)]
- 8. No person who has been associated with the use or promotion of prenatal diagnostic techniques for the determination of sex or sex selection (including those who might have a case pending against them) shall be appointed as a member of the Advisory Committee [Section 17 (7)]
- 9. No person against whom a case is pending in any court of law especially pertaining to the PCPNDT act be appointed as member of Appropriate Authority [Rule 18A (4) (ii)]
- 10. Further, it is to be ensured that a person who is part of investigating machinery in cases under the PCPNDT act, 1994 shall not be nominated/appointed as member of advisory committee [Rule 18A (2) (ii)].



4. Guidelines for Registration, Renewal, and Rejection of Registration

It is mandatory for all Genetic Clinic/Genetic Lab etc. or other facilities with the potential of sex selection to get registered as per Section 18 and 19 and Rules 4, 5,6, 7, and 8 and Appropriate Authorities to identify all the facilities including Genetic Laboratories, Genetic Counselling Centres, Genetic Clinic together with clinic, laboratory or centre having ultrasound or imagining machines or scanner or any other technology capable of undertaking determination of sex of the foetus and sex selection before and after conception or render services to any of them, in the region by conducting surveys and get them registered as per Sections 18 and 19 and Rules 4, 5, 6, 7, 8.



How to register facilities?

- Appropriate Authorities shall accept applications in the prescribed format (Form 'A' at annex 1 [Section 18 (2) Rule 4 (i) and Rule 8 (1)]
- Application to be accompanied by affidavit as per Rule 4 (1) [Sample format of the affidavit is at annex 2] containing undertaking that the Laboratory/Genetic Centre/Ultrasound Clinic shall not conduct any test or procedure for selection of sex, before or after conception nor disclose the sex of foetus to anybody except in case of diseases such as chromosomal or genetic disorders as specified in the Section 4 (2) of the Act
- The application shall be received by the Appropriate Authority and acknowledgement slip shall be duly issued. In the case of application received by post, acknowledgement slip shall be issued not later than next working day
- Application fees, as prescribed under Rule 5 (a) and 5 (b), are to be paid by Demand Draft drawn in favour of the Appropriate Authority on any Scheduled Bank payable at the Headquarters of the Appropriate Authority concerned as follows-
 - 1. Rs. 25,000 for Genetic Counselling Centre/Genetic Lab/Genetic Clinic/Ultrasound Clinic/Imaging Centre
 - 2. Rs. 35,000 for an Institute, Hospital, Nursing Home or any place providing jointly the service of Genetic Counselling Centre, Genetic Lab. And the Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof
- Provided, if any application for registration is rejected by the AA, no fee shall be required to be paid for the same facility on resubmission of the application within 90 days of rejection. Provided also, that any subsequent application (after 90 days of rejection) shall be accompanied with required fees
- As per the Code of Conduct for AAs, applications for fresh registration or renewal should be disposed off within a period of seventy days from the date of receipt of application; [Rule 18A (4) (i)]

- Registration certificate shall be issued in duplicate in the prescribed Form B [at annex 3]
- It is mandatory for the centre to display one copy of the registration certificate in a conspicuous place (near the machine) at its place of business. [Section 19(4), Rule 6 (2)]
- The registration certificate is non-transferable. In case of change of ownership, management, or the closure of the centre, both copies of the registration certificate of the clinic shall be surrendered to the Appropriate Authorities [Rule 6 (6)]
- In the event of a change of ownership or management, the new owner or management shall apply afresh for registration [Rule 6 (7)]
- The registration certificate is to be valid for a period of 5 years from the date of its issue [Rule 7]
- AA to maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H at annex 4 [Rule 9 (5)] Letters of intimation of every change of employee, place, address, and equipment installed shall also be preserved as permanent record.

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Format for Certificate of registration for mobile medical unit-

Name and Type of the centre, area of operation (not to exceed the district wherein it is registered, the number of portable machines installed and being used in the vehicle, detailed information regarding the machines (model No. make and full description of all machines and Probes), registration number of vehicle for the mobile medical unit [Rule 6 (2A) (b)].

The portable equipment used for conducting prenatal diagnostic test shall be an integral part of mobile medical unit and such equipment shall not be used outside such unit under any circumstances.

- One copy of the registration certificate shall be displayed by the registered mobile medical unit inside the vehicle at a conspicuous place
- In case of break down of vehicle or for any other reason due to which the registered unit cannot be used as a Genetic Clinic, the Appropriate Authority has to be informed with in a period of seven days. [Rule 6 (2A) (2B) (2C)]
- The provisions pertaining to renewal and fresh registration mentioned above for centres/facilities shall also apply in the case the mobile medical unit too

How to renew the registration?

- The application for renewal of certificate of registration should be made by the centre in duplicate in Form 'A' 30 days before the expiry of the registration period
- The process of renewal should be the same as the process of fresh registration [Rule 8 (2)]

- The fee of renewal should be half of the fees charged for new registration depending of the type of facility registered [Rule 8 (4)]
- On receipt of the renewed certificate or on receipt of rejection of application for renewal, the centre should surrender the earlier certificate of registration to the Appropriate Authority [Rule 8 (5)]
- If the applicant is not informed of the decision within 90 days of submitting the application for renewal, the registration is deemed to be renewed [Rule 8 (6)].

How to reject an application for registration or renewal?

- If a centre is found to be ineligible for registration or renewal, application shall be put up before the Advisory Committee for discussion
- Based on the advice of the Advisory Committee, and after giving an opportunity of being heard to the applicant, Appropriate Authority may reject an application for registration /renewal for reasons recorded in writing, if the applicant has not complied with the requirements of the Act and the Rules [Rule 6 (3)]
- Rejection of the application shall be communicated to the concerned party in Form C [at annex 5]. Form C is applicable both for both rejecting of new registrations as well as rejecting renewal of registration. Rule 6(3) and 8 (3).



How to utilise the application and renewal fee?

The fees collected by the Appropriate Authority for registration /renewal of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre or any other body or person under sub-rule (1), shall be deposited in a bank account in the name of the official designation of the Appropriate Authority concerned and shall be utilised by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and Rules [Rule 5 (2)].



5. Guidelines for Inspection of Facilities

How to inspect ultrasonography centres/genetic laboratories/genetic counseling centres?

Ensure that proper preparatory planning has been undertaken, prior to the inspection. The AA or any officer authorised in his/her behalf to carry with him/her during inspection, a copy of his/her notification as AA, an ID card, essential reference documents pertaining to the clinic such Forms A, B, H as well as past correspondence and letters received from the concerned centre/clinic owner.

Following things need to be examined during inspection of a Centre (indicative list not exhaustive): [Also refer to the indicative checklist for inspection of facilities at annex 6]

- Board is displayed prominently on its premises with text in English and the local language saying, 'Disclosure of the sex of the foetus is prohibited under the law'[Rule 17 (1)]
- Copy of the Act and Rules available on premises (and to be made available to clientele on demand for perusal) [Rule 17 (2)]
- Registration Certificate displayed in a conspicuous place (near the machine) at the place of business [Rule 6 (2)]
- Name and designation of the person using the equipment is to be displayed prominently on the dress/coat worn by him/her [Rule 18 (viii)]
- Details to be checked in the Registration application, certificate and other related documents (as per Form B)
 - i. Validity of certificate of registration
 - ii. Name and educational qualifications of the persons authorised to use the equipment or machine
 - iii. Information about the ultrasonography machine or similar equipment such as number, make model, including probe/s
 - iv. Prenatal diagnostic procedures approved for the centre
- **Details to be checked in case of facilities with portable machine/s**(portable machine to be used for indoor patients or as a part of the mobile medical unit or MMU)
 - i. Area of operation
 - ii. Number of portable machines installed and/or used
 - iii. Make and model of the portable machine/s

- iv. Registration of the vehicle that is the mobile medical unit in which the portable machine/s is available. Confirm that the registration number of the vehicle is the same as the one mentioned in Form B (registration certificate)
- v. Full address of the service providers
- vi. Availability of other services mandated by the PC&PNDT law in MMU.
- Review of the records at the centre/facility
 - i. Review of Form 'F' (Genetic clinics/Ultrasonography centres) [Form F at annex 7]
 - a. All the relevant points in the F form are filled and the form is duly signed by the Gynaecologist/Radiologist/Registered Medical Practitioner performing the procedure with his/her name, seal, number as per the Act
 - b. Copy of the F form (including the complete information about the pregnant woman) is sent to the Appropriate Authority before the 5th(date) of every succeeding month
 - c. Declaration of the pregnant woman is obtained in the language she understands when non-invasive techniques such as ultrasonography have been used
 - d. Consent letter obtained from the pregnant woman in the language she understands, when invasive techniques such as Amniocentesis have been used
 - e. Declaration is submitted by the doctor/s with time and date
 - f. Referral records along with the copy of films of scans are maintained
 - g. OPD register along with the ANC register and cash receipts
 - h. Review computer records along with the hard copies of the records.

The Central Supervisory Board in the meeting held on 17th October 2005 recommended developing mechanisms so that form F can be filled/ submitted online. Subsequently, some state governments have made it mandatory to fill 'F' forms online. In such cases, along with online filling of the forms, a hard copy of each form must be maintained at the centre/facility along with the signed declaration/consent letter (as the case may be) of the pregnant woman and the declaration of the doctor.

- ii. Review of Form 'D' (Genetic Counselling centres) [Form D at annex 8]
 - a. All relevant points are filled
- b. Forms have been submitted by the 5th (date) of every month to the Appropriate Authority [Rule 9 (8)]
- iii. Review of Form 'E' (Genetic Laboratories) [Form E at annex 9]
 - a. All relevant points are filled
 - b. Consent obtained from the pregnant woman in Form 'G' [at annex 10]
 - c. Forms have been submitted by the 5th (date) of every month to the Appropriate Authority [Rule 9 (8)].

- Tally Form 'F' with the OPD Register [Rule 9 (1)] to ensure that there is no discrepancy in the number of patients examined and the total number of statutory forms filled
- After the inspection, if any lapses are found, the AA is expected to take necessary steps to address the violation [Section 30 read with Rule 12 (1)]
- Issue a show cause notice seeking explanation as to why registration of the centre should not be suspended/cancelled [Section 20 (1)]. Sample format for issuing a show cause notice can be found at Annex 11. Guidelines on suspension and cancellation of registration are at annex 12 [Please also refer to the key sections of the law pertaining to inspection and issuance of show cause notice in the box below]
- If applicable, as per Section 30, complete the legal procedure of search, and seize the Record and the Ultrasonography machine [Rule 12 (1)]
- File a case with the Judicial Magistrate First Class/metropolitan magistrate [Section 28]. Sample format for filing a case is at annex 13.

Relevant Sections of the Law concerning Inspections

- Appropriate Authorities have the right to take appropriate legal action against the use of any sex selection/determination techniques by any person at any place, if it is found that the centre or the person has contravened the Act. Such action can be taken by the Appropriate Authorities, on their own or on receiving information to that effect and after carrying out necessary inspection [Section 17 (4)(e)]
- With regard to authorizing AA to undertake inspection outside his/her jurisdiction, as per section 462 CrPC, no finding, sentence or order of any Criminal Court shall be set aside merely on the ground that the enquiry, trial or the proceedings in the course of which it was arrived at or passed, took place in a wrong sessions division, district, subdivision or other local area unless it appears that such error has in fact occasioned a failure of justice
- Appropriate Authorities shall issue to a centre violating the law, a show cause notice on their own or after receiving a complaint. In the notice, they will ask for an explanation as to why the registration of the said centre should not be suspended/cancelled [Section 20 (1)]
- Following a show cause notice and after giving sufficient time and reasonable opportunity of being heard, the Appropriate Authorities should put up the matter before the Advisory Committee for advice and subsequently, the registration of such a Ultrasonography Centre/ Genetic Laboratory/Genetic Counselling Centre should be suspended/cancelled [Section 20 (2)]
- Although Section 20 (1) and (2) requires the Appropriate Authorities to serve notice, they hold the right to suspend the Registration of any centre without serving any notice, if it is in the public interest to do so and after citing reasons for doing so [Section 20 (3)]
- Following the action taken against a centre/facility under Section 20(3), issue a show cause notice as to why the registration of the centre should not be cancelled. Provide an opportunity to the facility owner to be heard and give an explanation in response to the show cause notice. Thereafter, follow procedure mentioned under Section 20(1) and 20(2) for cancellation of registration and proceed to file a court case.



6. Search and Seizure Operations



How to undertake search and seizure operations?

- Appropriate Authorities hold the right to enter and search at all reasonable times any Genetic Laboratory/Genetic Counselling Centre/Ultasonography Centre which is suspected to have contravened the Act and examine all registers, documents, receipts, books, pamphlets, advertisements or machines and other equipment, and seize and seal these, if the AA believes that these are likely to furnish evidence related to a commission of offence [Section 30 (1) and Rule 12]
- The relevant provisions of Code of Criminal Procedure, 1973 [at annex 18] and guidelines as per Section 30 [annex 12] are to be followed in carrying out search and seal [Section 30 (2)]
- A sample format of seize and seal Panchnama/seizure memo and a sample format for cancellation/suspension of registration is also enclosed [at annex 12]
- Seizure memo contains a list of documents and other material or object found and seized, prepared in duplicate at the place of seizure and signed on every page by the AA or by the officer so authorised on his/her behalf and by the witnesses [Rule 12 (2)]
- One copy of such a seizure memo is to be given to the person from whose custody these documents and other material and objects have been seized and acknowledgement obtained for handing over the copy of the memo with the list [Rule 12 (3)]
- If no person is available to receive a copy of the seizure memo, it may be delivered through registered post to the owner/manager of the centre
- If material seized is of a perishable nature, arrangements to be made for prompt seizing and preservation as well as sending to the concerned facility for analysis and tests as required [Rule 12 (4)]
- If for any reason the search and seizure operation is not completed, the AA can make arrangements for mounting a guard, removing seized documents from the premises and sealing the premises to avoid tampering with possible evidence [Rule 12 (5)].

Relevant Sections of the Law concerning Search and Seize

- It is mandatory for owners/operators/doctors to allow the Appropriate Authorities to conduct search operations in registered/unregistered hospital, home, vehicle, shop, etc. and make available all documents, machinery, equipment, etc. for inspection [Rule 11 (1)]
- Appropriate Authorities are authorised to seal and seize any ultrasound machine, scanner or any other equipment capable of sex determination, if the concerned facility or centre is found to be unregistered. The machine will be sealed, confiscated (Rule 11 (2) and action taken under Section 23 of the Act, implying that the concerned machine or equipment shall become the property of Government. The procedure for confiscation would be done after giving the concerned person reasonable opportunity of being heard and the concerned machine/ equipment cannot be de-sealed without a Court order
- The Appropriate Authority or any officer authorised on his/her behalf may enter and search at all reasonable times Genetic Counselling Centre, Genetic Clinic, Imaging centre or ultrasound clinic in the presence of two or more independent witnesses for the purpose of search and examination of record, register, documents, pamphlet, advertisement or any other material object found therein and seal and seize the same if there is reason to believe that they may furnish evidence of commission of an offence punishable under the act. Rule 12(1)
- For any action taken under the provisions of the Act in good faith, no criminal action shall be initiated against the state government/Appropriate Authority or any other officer authorised by the state/central government/authority for anything done/intended to be done in good faith [Section 31].



How to undertake a decoy operation to generate evidence, when intelligence has been gathered about a centre or a facility that is conducting or aiding illegal sex selection? Also refer to detailed guidelines on conducting decoy operations [at annex 16]

- Choose a trustworthy woman who is 14 to 22 weeks pregnant. Explain the gravity of the situation to her in a language she understands and take her consent to participate in a decoy operation [Sample Format for the undertaking from a pregnant women acting as the decoy client can be referred at annex 14]
- Take permission from her relatives (husband, mother in law, mother). They should also be explained the process and counselled in a language they understand
- A pre-trap or pre-decoy seizure memo/Panchnama may be prepared and an affidavit from the pregnant woman should be obtained stating that she is ready to take part in such an operation
- Note the numbers on the currency notes to be used for the decoy operation. These currency numbers are to be mentioned in the Pre-trap Panchnama/affidavit. Give these currency notes to the decoy woman or the witnesses. Make sure the decoy does not have any other currency notes except those provided for the operation
- Prepare two witnesses to accompany the woman
- Keep an audio-video system hidden and handy, if possible. If a video camera is being used, it needs to be left on during the entire course of the operation, including post-decoy investigation
- The pregnant woman and the witnesses should be trained to operate the audio-video equipment correctly and should be comfortable in using it
- Useful to keep three main witnesses and two observers ready as a team. They should be friendly enough with each other to work as a team, with excellent nonverbal communication. They should be trained so as to gather and collect evidence, have a good knowledge of the Act and learn how to play an effective role in the success of the decoy operation
- (If needed) phone numbers of nearby police station and Police officers should be kept handy. Police incognito (in plain clothes) protection should be sought in case it is needed
- Concerned Appropriate Authorities or officer authorised by appropriate authority of that jurisdiction should be available close by where the decoy operation is to take place and intervene as soon as they are informed

- Upon learning that the decoy operation is successful, the Appropriate Authority should exercise due caution and keep the facility owner/staff under constant observation
- It should be ensured that the accused is not able to make phone calls to anybody. All his/her phones and communication devices should be switched off
- The AA should locate the currency notes used for the operation, verify the numbers and keep them in record after Panchnama [Sample format of a Panchnama concerning a decoy operation is at annex 15]
- AA should record the statement of the accused in writing or in his/her handwriting after inquiry
- Statements from the co-accused (other paramedical staff, agent, PRO) should also be recorded
- The centre should be thoroughly inspected and all important documents should be seized and sealed. The entire premises, house, garage, hospital should be thoroughly searched for any unregistered machine/or any other contravention of the PCPNDT Act
- All authorised, unauthorised machines should be taken into custody. Physically the seized machine will remain in the possession of the owner of facility but effectively, it will be in custody of Appropriate Authority. Further, it will be handed over to the owner whose responsibility will be to ensure non-tampering of the seal and non use of machine till further orders. After the Panchnama, the accused should be given an acknowledgment in writing of all seized machines, documents and other materials and objects
- A comprehensive and thorough Inspection report should be prepared (to refer to the checklist for inspection at annex 6 of these guidelines)
- At the place of the crime, statement of the pregnant woman and the witnesses should be recorded and all the evidence in the form of audio, videocassettes should be taken into custody
- If the audio and video recording has been done, a CD should be made and submitted in the Court at the time of filing the case. No changes should be made in the contents of the audio/video recording. The entire conversation should be transcribed on paper and submitted along with the case
- All documents such as Certificate of Registration (both in original), board, form 'F', affidavit of the pregnant woman, doctor's declaration, OPD register, birth register, a copy of the Act, referral slips and related communication, documents related to registration, documents relating to the Ultrasonography machine should be seized. All the exchange of letters between the accused and the Appropriate Authority should be taken into custody
- Statements of any patients, relatives, expecting 'sex selection services' as were offered to the decoy pregnant woman, who are found present at the place, should also be recorded along with their addresses and contact information. They should be called during the investigation, if needed

- After ensuring that the investigation has been carried out thoroughly, a complaint should be filed in the concerned Court by the Appropriate Authority as soon as the investigation is completed, enclosing all the documents including evidence collected during decoy operation and investigation
- As the Appropriate Authority is the complainant, the Appropriate Authority or his/her authorised representative should be present in the Court at all times for the hearing of the case.



8. Guidelines for Responding to a Complaint

How to respond to a complaint regarding violation of the PCPNDT Act?

- After receiving a complaint, all investigations concerning it should be started within twenty-four hours of receipt of complaint and completed within forty-eight hours of the receipt of the complaint (as per Code of Conduct for AAs)
- Original documents should be taken in possession and acknowledgment of the documents received should be given to the complainant[Rule 18 A(3) (iii)]
- If the complaint is anonymous and the complaint has been made through a phone call or on an online reporting website, an email or a letter, all details such as phone numbers, time of the complaint, date should be noted and a hard copy of the complaint must be kept on record, along with related documentation for example the envelope that came with the letter
- On the basis of the complaint, an inspection of the facility/centre should be carried out. Inspections should be completed as per the Rules and inspection report should be prepared [Rule 12 (1) (2)] Also refer to the indicative checklist for inspection at annex 6
- If a centre is found to have contravened the law, its registration should be suspended immediately as per Section 20(1), (2), (3) and search and seize procedures should be completed
- Statements of witnesses should be recorded. Panchnama should be prepared after gathering evidence
- Statement of witnesses and the complainant should be filed as evidence. Complainant should be cited as a witness for the prosecution
- Procedure should be completed as per the law and a case should be filed in the Court of Judicial Magistrate First Class/Metropolitan Magistrate [Section 28(2)]
- FIR should be avoided under the PC&PNDT Act as there is no direct role of police in the Act [Rule 18A(3) (iv)]
- Ensure that there shall be no violation of the provisions of the Medical Termination of Pregnancy Act, 1971 (34 of 1971) and the Rules made thereunder while implementing the provisions of the Pre-conception Prenatal Diagnostics Techniques (Prohibition of Sex Selection) Rules, 1996 [Rule 18A (5) (v)].

Points to Remember

- (1) If the complaint has been received by the Appropriate Authorities as a 15 days' notice issued by a social organization, journalist or an individual, as per Section 28 (1)(b) of the Act, the Appropriate Authorities should take action based on the complaint. Failing to do so would mean the person (includes a social organization) making the complaint directly to the Court and will also mean a breach of Section 17 that details the responsibilities of the Appropriate Authority
- (2) As per Section 24, no action shall be taken against the pregnant woman. She is protected under the law.



9. Guidelines for Filing a Criminal Complaint

How to file a criminal complaint under the PCPNDT Act?

As per section 28 of PCPNDT Act the Appropriate Authorities are authorised to file a criminal complaint in the Court of Judicial Magistrate First Class/Metropolitan Magistrate. The process of filing a complaint case has been divided into four segments:

- A) Preparatory processes prior to filing a complaint case
- B) Documents to be submitted or annexed with the complaint
- C) Actual filing of the case
- D) General instructions

A) Preparatory Processes

- The Appropriate Authority or any person authorised by the Appropriate Authority may inspect any centre. During inspection if the inspecting authority finds a violation of Provisions of the Act, they should mention all the violations of the Act and draw seizure memo/Panchnama with the help of independent witnesses [Rule 12]
- Panchnama should be drawn in the presence of Panchas. Witnesses are only to identify seized/witnessed by them
- If the inspecting authority finds it necessary to seal and seize materials, including the machine and records, this should be done in accordance with the law. Inspecting authority should supply one copy of the list of sealed & seized objects and obtain an acknowledgement from the owner of the centre or a person authorised on his/her behalf [Section 30 Rule 12 (3)]
- AA should issue a show cause notice for violations found in the centre and call for explanation from the owner of the centre. Explanation should be considered in the Advisory Committee and recommendation for cancellation/suspension of the registration of centre should be made to Appropriate Authority. Appropriate Authority should suspend or cancel the registration of centre by providing reasons for the action taken
- If AA has reason to believe that the machine or any object may furnish evidence of the commission of an offence then they may seal the machine or other objects as well. In such cases, the reason has to be recorded in writing for such action being necessary in the public interest and the registration of the centre should be suspended without giving any notice in the interest of law [Section 20 (3)]
- In other cases (except in matters of public interest), while suspending registration the authority should issue a show cause notice and call for explanation in a stipulated time.

The explanation should be put forth for consideration of the Advisory Committee for deciding

- a. Cancellation of registration of centre
- b. Initiation of Court proceeding as explanation provided in response to the show cause notice was not found satisfactory
- If the owner of the centre or the facility or the sonologist, assistant/employee gives any confession admitting the offence, it should be properly recorded in writing and duly signed by the owner or the person authorised on his/her behalf. If this is not possible then the statement recorded by anybody on the scene needs to be read by the owner, and if that too is not possible (in case disease, ill-health, illiteracy, etc.), the same should be read to him/her and explained and his/her signatures to be taken on it by mentioning that he/she has understood the contents of the statement after it was read to him/her and he/she has signed the it willfully, fully conscious of the content and without any coercion or undue influence. This will be helpful for proving the case.

The inspecting authority should draw up a detailed report of the inspections with accurate date and time and place and preferably with a site plan.



B) Documents to be submitted or annexed with the complaint:

[Pl also refer to the indicative checklist to ascertain completeness of legal documentation for filing a Case at annex 17. **Pl. note that documents are to be submitted in original as mentioned in the checklist**]

It is necessary to submit accurate and complete documents in the Court of Law. The following list of documents must be submitted

- a. Notification of Appropriate Authority in Government Gazette should be submitted in original. (Section 17(1)
- b. Authorisation letter by the Appropriate Authority in case of inspection by authority or person authorised by Appropriate Authority. The letter should contain date and specific area for inspection, preferably with a site plan
- c. Inspection report with all seizure memos
- d. Show cause notice issued by Appropriate Authority (Sec 20(1)
- e. Panchnama, sealed and seized documents /objects(seizure memo) with the list
- f. Statement of centre owner
- g. Explanation of centre owner
- h. Recommendation of Advisory Committee
- i. Order of Suspension and/or cancellation of registration
- j. Any other documents which are found during inspection.



C) Actual filing of the complaint:

The complaint must be filed by the Appropriate Authority or the officer so authorised [Sample format for filing of the complaint at is at Annex 13]

- a. During filing of the case the Appropriate Authority should take all the papers to the legal expert and draft a complaint in consonance with the facts of the inspection
- b. This procedure should be followed under the guidance of the legal expert who is member in the Advisory Committee/Assistant Public Prosecutor/District Public Prosecutor/ Special Public Prosecutor as the case may be and documents vetted by the legal expert before filing of the complaint
- c. All factual aspects should be narrated in the complaint and law should not be pleaded
- d. All necessary people should be made an accused and proper addresses should be mentioned in the complaint
- e. Proper process fee should be submitted in court after the summoning order is passed. All necessary legal fees and process fee to be paid from the account of PCPNDT
- f. All original documents should be submitted. One copy of the documents should be kept with the Appropriate Authority and concerned lawyer/ Public Prosecutor before submission
- g. Copy of the documents should be provided to the accused as and when directed by the court
- h. Proper RCC (Registered Complaint Case) Number should be obtained with the help of superintendent of the Court and allotment of the case should be checked. Proper next date should be obtained. This date and Court name and court proceedings should also be mentioned in the file with the Appropriate Authority.

D) General instructions:

- a. Witnesses and Panchas should be trustworthy and independent so that the risk of them turning hostile during the trial is minimised
- b. Date and time of inspection is crucial, hence it should be properly cited
- c. Ensure that all points of inspection have been covered during inspection. Use checklist of inspection to ensure completeness (Annex 6)
- d. Ensure that stipulated time is given to the owner of the centre or facility for providing explanation and order of cancelation or suspension should not be passed during this stipulated time
- e. It is necessary to confirm that all necessary papers and complete documentation is submitted to the Court. Incomplete paperwork, including photocopies of documents must be avoided
- f. Original documents should be submitted and it should be mentioned in the Court that the authority is submitting original papers. All those papers should get exhibited. A photocopy of the complete set of papers has to be kept with the Appropriate Authority

- g. A proper follow up of the Court Case by the designated person and regular discussion with the Assistant Public Prosecutor is a must to ensure conviction
- h. It is the responsibility of the Appropriate Authorities to maintain a daily diary of the case
- i. Once the charges are framed, application for suspension of the registration of the doctor should be submitted to the State Medical Council along with the certified copy of the framed charges [Section 23 (2)], and on conviction, for the removal of his/her name from the register of the Council for a period of five years for the first offence and permanently for the subsequent offence.

ANNEXURES

Section I: Guidelines and Formats

¹FORM A

[(Refer rules 4(1) and 8(1)]

(To be submitted in Duplicate with supporting document enclosures

Application for registration or renewal of a genetic counseling centre/genetic laboratory/ genetic clinic/ultrasound clinic/imagine centre

1. Name of the applicant

(Indicated name of the organization south to be registered)

- 2. Address of the applicant
- 3. Type of facility to be registered

(Please specify wheatear the application is for registration of a Genetic Counseling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre or any combination these)

- 4. Full name and address/ addresses of Genetic Counseling Centre/Genetic Laboratory/ Genetic Clinic/ Ultrasound Clinic/Imaging Centre with Telephone/Fax number (s) Telegraphic/Telex/Email address (es)
- 5. Type of ownership of Organization (individual ownership/partnership/company/ co-operative/any other to be specified). In case type of organization is other than individual ownership, furnish copy of articles of association and names and address of other person responsible for management, as enclosure
- 6. Type of Institutions (Govt. Hospital/Management/Municipal Hospital/Public Hospital/ Private Laboratory/any other to be stated)
- 7. Specific pre-natal diagnostic procedures/tests for which approval is sought
 - (a) Invasive
 - (i) Amniocentesis/chorionic villi aspiration/chromosomal/biochemical/molecular studies
 - (b) Non-Invasive Ultrasonography

Leave blank if registration is sought for Genetic Consoling Centre only

8. Equipment available with the make and model of each equipment (List to be attached on a separate sheet)

^{1.} Substituted vide GSR 109 (E), dt. 1-2-2003, w.e.f. 14-2-2003.

- 9. (a) Facilities available in the Counseling Centre
 - (c) Whether facilities are or would be available in the Laboratory/Clinic for the the following test:
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic villi aspiration
 - (iv) Foetoscopy
 - (v) Foetal Biopsy
 - (vi) Cordocentesis

Whether facilities are available in the Laboratory/Clinic for the following:

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies
- (iv) Preimplatation genetic diagnosis
- 10. Names qualification experience and registration number of employee (may be furnished as an enclosure)
- 11. State whether the Genetic Consoling Centre/Genetic Laboratory/Genetic Clinic/ ultrasound clinic/imaging centre¹ qualifies for registration in term of requirement laid down in rule 3
- 12. For renewal application only:
 - a. Registration No.
 - b. Data of issue and date of expiry of existing certificate of registration
- 13. List of Enclosures

(Please attach la list of enclosures/supporting documents attached to this application.)

Date:

Place:

(.....)

Name, designation and signature of the person

Authorised to sign on behalf of the organization to be registered.

¹ Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant

DECLARATION

I also undertake to explain the said Act and Rules to all employees of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound clinic/imaging centre in respect of which registration is sought and to ensure that Act and Rules are fully complied with.

Date:

Place:

(.....) Name, designation and signature of the person Authorised to sign on behalf of the organization to be registered

² Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"

^{3.} Read as "The Pre-conception and Pre-natal Diagnostic (Prohibition of Sex Selection) Rules, 1996"

[SEAL OF THE ORGANIZATION SOUGHT TO BE REGISTERED] ACKNOWLEDGEMENT

[Refer rules 4(2) and 8(1)]

The application in Form A in duplicate for grant*/renewal* registration of Genetic Counseling Centre*/ Genetic Laboratory*/Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre* by...... (Name and address of applicant) has been received by the Appropriate Authority on date).

*The list of enclosures attached to the application in Form A has been verified with the enclosures submitted and found to be correct.

OR

*On Verification it is found that following documents mentioned in the list of enclosures are not actually enclosed.

This acknowledgement does not confer any right on the applicant for grant or renewal of registration.

(.....)

Signatures and Designation of Appropriate Authority or authorised person in the Office of the Appropriate Authority

Affidavit under Rule 4(1) of the PCPNDT Act

(Submitted along with application for registration)

| IS/o | aged about years, owner of |
|---|----------------------------|
| (Clinic name/address) | do hereby |
| solemnly affirm and declare as under that | |

- 1. The Genetic Centre/ Laboratory/ Clinic /Combination owned by me shall not conduct any test or procedure, by whatever name called for selection of sex before or after conception or for detection of sex of foetus except for diseases specified in Sec 4(2) of the PCPNDT Act, 1994 and shall not disclose the sex of the foetus to anybody.
- 2. The Genetic Centre/ Laboratory/ Clinic /Combination owned by me shall display a notice that we do not conduct any technique, test or procedure for detection of sex of foetus or for the selection of sex before or after conception.

DEPONENT

VERIFICATION

Verify that the contents of the above are true and correct to the best of my knowledge and belief. Nothing is false and nothing has been concealed there from.

Verified at _____ on ____this day of ____201

DEPONENT

¹FORM B

[Refer rules 6(2), 6 (5) and 8 (2)] CERTIFICATE OF REGISTRATION (To be issued in duplicate)

- In exercise of the powers conferred under section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)², the Appropriate Authority _______ hereby grants registration to the Genetic Counseling Centre/Genetic Laboratory*/Genetic Clinic*/ Ultrasound Clinic*/Imaging Centre* named below for purposes of carrying out Genetic Counseling/Pre-natal Diagnostic Procedure*/ Pre-natal Diagnostic Test/ultrasonography under the aforesaid Act for a period of five years ending on........
- 2. This registration is granted subject to the aforesaid Act and Rules there under and any contravention there of shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.
 - A. Name and address of the Genetic Counseling Centre*/Genetic Laboratory*/Genetic Clinic*/ Ultrasound Clinic*/Imaging Centre*.
 - B. Pre-natal diagnostic procedures* approved for (Genetic Clinic).

Non-Invasive

(i) Ultrasound

Invasive

(ii) Amniocentesis

- (iii) Chorionic Villi biopsy
- (iv) Foetoscopy
- (v) Foetal Skin or organ biopsy
- (vi) Cordocentesis
- (vii) Any other (specify)
- C. Pre-natal diagnostic test* approved (for Genetic laboratory).
 - (i) Chromosomal studies
 - (ii) Biochemical
 - (iii) Molecular studies
- D. Any other purpose (Please Specify)

- 3. Model and make of equipment being used (any change is to be intimated to the Appropriate Authority under rule 13)
- 4. Registration No. allotted.
- 5. Period of validity of earlier Certificate Registration. (For renewed Certificate or Registration only)

From...... To

Signature, name and designation of the appropriate Authority SEAL

Date:

^{1.} Substituted vide GSR 109 (E), dt. 1-2-2003, w.e.f. 14-2-2003.

^{2.} Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"

¹FORM H

[Refer rule 9(5)]

MAINTENANCE OF PERMANENT RECORD OF APPLICATION FOR GRANT/REJECTION OF REGISTRATION UNDER THE PRE-NATAL DIAGNOSTIC TECHNIQUE (REGULATION AND PREVENTION OF MISUSE ACT, 1994²

- 1. Sl. No.
- 2. File Number of Appropriate Authority
- 3. Date of receipt of application for grant of registration
- 4. Name, Address, phone/Fax etc. of Applicant
- 5. Name and address of Genetic Counselling Centre*/ Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/Imaging Centre
- 6. Date of consideration by advisory committee and recommendation of advisory Committee, in summary
- 7. Outcome of application (state granted/rejected and date of issue of orders record date of issue of order in Form B or Form C)
- 8. Registration number allotted and date of expire of registration.
- 9. Renewals (date of renewal and renewed upto)
- 10. File number in which renewals upto)
- 11. Additional information, if any

Name, Designation and Signature of Appropriate Authority

Guidance for Appropriate authority

- (a) Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority
- (b) *Means strike out whichever is not applicable
- (c) On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management

- (d) Registration number shall not be allotted twice
- (e) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre may be allotted a folio consisting of two pages of the Register for recording Form H
- (f) The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.
- (g) Every folio (i.e. pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.)

Note: The Principal Notification was published in the Gazette of India vide No. GSR 1 (E), dt. 1-1-1996 and amended vide Noti. No. GSR 119(E), dt. 24-2-2014.

^{1.} Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f 14-2-2003

^{2.} NOW "THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994"

¹FORM C

[Refer rules 6(3), 6 (5) and 8 (3)] Rejection of Application for Grant/Renewal of Registration

In exercise of the powers conferred under section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994², the Appropriate Authority....... hereby rejects the application for grant*/renewal*/of registration of the under mentioned Genetic Counseling Centre*/ Genetic Laboratory*/Genetic Clinic*/ Ultrasound Clinic*/Imaging Centre*.

- 1. Name and address of the Genetic Counseling Centre*/ Generic Laboratory*/ Genetic*.
- 2. Reasons for rejection of application for grant/renewal of registration:

Signature, Name and designation of the Appropriate Authority with SEAL of Office

Date:

Place:

*Strike out whichever is not applicable or necessary

^{1.} Substituted vide GSR 109 (E), dt. 1-2-2003, w.e.f. 14-2-2003.

^{2.} Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"

Indicative Checklist for Inspection of Facilities Under the PCPNDT Act, 1994

A. General Information:

| Date and time of Inspection: | Date: | Time: |
|--|-------|-------|
| Names/designation of the inspecting | | |
| authority or details of team members, if | | |
| applicable: | | |
| Name: | | |
| | | |
| Designation: | | |
| Name: | | |
| | | |
| Designation: | | |
| Name: | | |
| | | |
| Designation: | | |
| Name of the facility: | | |
| Name of the facility owner: | | |
| Type of facility (genetic clinic, genetic | | |
| counseling centre, genetic laboratory, | | |
| ultrasonography centre, imaging facility and | | |
| combinations if any, pl. specify) | | |
| Address of the facility(Complete): | | |
| Telephone/mobile: | | |
| E-mail | | |

B. Information about the facility:

| S. | Things to be seen/ checked | Observations |
|------------|--|--|
| No. | | |
| A1 | Is the facility registered | Yes/No |
| | If yes: Date of registration (dd/mm/yy) | |
| | 1.1. Registration certificate/s number and validity date | |
| | 1.2. In cases registration certificate has lapsed whether | Yes/No |
| | the application for renewal has been submitted? | |
| | 1.3. If "No" then how long the facility has been | |
| | unregistered (owing to non-renewal or lack of | |
| | registration)and how many USGs has been performed | |
| D 4 | during this period (check the record) | |
| B1 | What kind of diagnostic equipment is available at the | If portable machine |
| | facility? List each equipment (such as ultrasound machine, including portable machine) separately with the make and | is registered with the clinic verify and probe |
| | model, no. etc | to ensure that machine |
| | | is being used within the |
| | | registered premises |
| | 1.1. Is/are the same equipment/s entered in the | Yes/No (list and |
| | registration certificate? | specify the details |
| | | of the equipments |
| | | not entered in the |
| | | registered certificate) |
| | 1.2. Has AA been informed about those equipments which | Yes/No |
| | have yet to be entered in the registration certificate? | \//\ _ |
| | 1.3. Has the owner sold any equipment after registration | Yes/No |
| | 1.4. If yes, has AA been informed about this equipment | Yes/No |
| | 1.5. (not relevant) | Yes/No |
| | 1.6. To whom the owner has sold the equipment (mention name of centre/person, complete address, date of sale, | |
| | telephone number) | |
| | 1.7. Is the facility to which the equipment has been sold | Yes/No |
| | registered under the PCPNDT Act? | 100/110 |
| | | Check registration |
| | | documents, proof sale, |
| | | etc |

| S. No. | Things to be seen/ checked | Observations |
|-----------|---|--|
| | 1.8. Is there any equipment sealed by DAA in the facility? | Yes/No |
| | 1.9. If yes, ensure that seal is intact and equipment is not | |
| | being misused. Mention findings | |
| | 1.10. Has there been voluntary commissioning/disclosure of any equipment? | If yes, verify and mention details |
| B2 | If the facility registered as a MMU? | |
| | 2.1 Is the vehicle in which equipment carried is registered with the DAA? | Yes/No |
| | 2.2. | Yes/No |
| | | Verify documents |
| | 2.3. Mention the jurisdiction of the MMU as per details | Probe with staff |
| | given in the application for registration. | the movements of |
| | | the MMU to ensure mobility within |
| | | approved jurisdiction |
| | 2.4 What bouquet of health and medical services are provided by the MMU, pl. specify? | |
| C 1 | Who is operating registered equipment: Name and Qualification | |
| | 1.1. Does the same name mentioned on the dress /coat of | If no, verify reasons and note violations |
| | the operator/doctor as per Rule 18 (1)? | of any |
| | 1.2. Verify those using the equipment are authorised by | Yes/No |
| | DAA to use diagnostic techniques under the Act | |
| | 1.3. Verify their registration certificate and qualifications | Yes/No |
| | as approved and as per the Medical Council of India/state 1.4. Do any of the operators of the equipment are also | |
| | authorised to conduct diagnostic techniques at other | |
| | facilities? Specify name, visiting schedule for other | |
| | facilities | |

| S. No. | Things to be seen/ checked | Observations |
|-----------|---|----------------------------|
| C2 | If the inspection is being undertaken for a genetic laboratory, the above questions need to be modified in reference to the law. In case of a genetic lab, <u>the focus will</u> not be on the equipment but the genetic tests undertaken carrying a possible potential of sex selection. Inspection to include Review registration details Review of equipment, service provided Review of records including test report, slides, etc. Confirm lab technicians/doctors are authorised to conduct genetic tests | |
| D1 | Review of affidavit Does this centre also provide MTP services | Yes/No |
| | 1.1. If yes, is the centre registered under MTP Act? | Yes/No |
| | 1.2. If yes, check registration certificate (And carry out inspection in separate MTP centre inspection form) | Available/Not available |
| E1 | PCPNDT registration certificate displayed at prominent place | Yes/No |
| | 1.1 Display of board stating – disclosure of the sex of foetus, is prohibited under the law. (in bold letters, in two languages- Local and English) at prominent place. | Yes/No |
| | 1.2 At least one copy of the PCPNDT Act is available at the facility | Yes/No |

F. Review of records and reports:

- 1. Has the centre submitted monthly report along with photocopies of the concerned forms (D,E,F,G) to District AA on 5th of the succeeding month for last 3 months and acknowledgement is available: Yes/ No (Verify F form copies)
- 2. Does the centre maintain records as per Rule 9 (1) : Yes/No.

If no, give details:

3. Number of Form F available in centre of last 3 months:

3.1. Tally some of the names in the OPD register with the F form (as a sample)

3.2. Numbers of diagnostic procedures reported in the monthly report during last 3 months:.....

- 4. Mention discrepancies, if any.
- 5. Number of Form "F" scrutinised: ------

5.1. No. of diagnostic techniques performed on pregnant women having only female children:

5.2. No. of diagnostic techniques performed on clients from outside the District/State:

E. Form "F" major observations:

Note: Pl. remember and verify that records for the last two years are available with the centre as per the law. 30 or 10% F forms whichever is more, must be scrutinised during the inspection and observations noted in the format below. To ensure effective use of the time available during inspection, only critical areas of F form have been listed below. Depending on the duration of the inspection and availability of team members, the inspecting authority may choose to undertake a more detailed inspection and ask for information beyond what is mentioned below

| S. No. | Contents | Serial. no. of "F" Forms found blank | Serial. no. of "F" Forms found incomplete information | Serial No. of "F" Forms found written correctly | Remarks |
|-----------|---|--|---|---|---------|
| 1 | Clients name and age | | | | |
| 2 | Number of previous children with sex of each child | | | | |
| 3 | Husband's/father's name | | | | |
| 4 | Full postal address with telephone number if any | | | | |
| 5 | Referred by- full name, address and qualification of the doctor | | | | |
| 6 | Self referral in case of gynaecologist is owner of USG Centre (Referral letter is available) | | | | |
| 7 | Last menstrual period mentioned and wks of pregnancy | | | | |

| S. No. | Contents | Serial. no. of "F" Forms found blank | Serial. no. of "F" Forms found incomplete information | Serial No. of "F" Forms found written correctly | Remarks |
|-----------|---|--|---|---|---------|
| 8 | Date/s on which the procedure carried out written correctly | | | | |
| 9 | For each non-invasive procedure, correctly filled in declaration form of pregnant woman is available and signed | | | | |
| 10 | Correctly filled in declaration form by the doctor conducting procedure is available and signed | | | | |
| 11 | Name/Signature and reg.no. of Gynaecologist/ Radiologist/ Director of centre is mentioned | | | | |

Name/signature/designation of team member-1

Name/signature/designation of team member-2

Name/signature/designation of team member-3

Signature of the owner or the person on whose name the facility is registered

| Date: | |
|--------|--|
| Place: | |

¹FORM F

[Refer proviso to section 4(3) rules 9(4) and 10(1A)]

FORM FOR MAINTENANCE OF RECORDS IN CASE OF PRENATAL DIAGNOSTIC TEST/ PROCEDURE BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

Section A: To be filled in for all Diagnostic Procedure Tests

| 1. | Name and complete address of the Genetic Clinic/Ultrasound Clinic/Imaging Centre: |
|----|--|
| 2. | Registration no. (Under PC & PNDT Act, 1994) |
| 3. | Patient's Name |
| 4. | Total Number of living Children |
| A. | Number of living Songs with age of each living son (in years or mont hs) |
| B. | Number of living Daughter with age of each living daughter (in year months) |
| 5. | Husband's/wife/Father's/Mother' Name" |
| 6. | Full Postal address of the patient with contact Number, if any |
| 7. | Referred by (Full name and addresses of doctor (s)/Genetic Counseling Centre (Referral Slips to be preserved carefully with form F) |
| | b. Self-Referral by Gynecologist/Radiologist/Registered Medical Practitioner Conducting the diagnostic procedure: |
| | (Referral note with indications and case papers of the patient to be preserved with form F) |
| | (Self-referral does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pregnant women) |
| 8. | Last Menstrual period or weeks of pregnancy: |
| Se | ction B: To be filled in for performing non-invasive diagnostic Procedures/Tests only |

- 9. Name of the doctor performing the procedure/s:.....
- 10. Indication/s for diagnosis procedures (specify with reference to the request made in the referral slip or in a self referral note)

(Ultrasonography prenatal diagnosis during pregnancy should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy. (Put "Tick" against the appropriate indication/s for ultrasound).

- i. To diagnose intra-uterine and/or ectopic pregnancy and confirm viability
- ii. Estimation of gestational age (dating)
- iii. Detection of number of foetuses and their chorionicity
- iv. Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
- v. Vaginal bleeding/leaking.
- vi. Follow-up of cases of abortion
- vii. Assessment of cervical canal and diameter of internal os.
- viii. Discrepancy between uterine size and period of amenorrhea
- ix. Any suspected adenexal or uterine pathology/abnormality

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003

- x. Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up
- xi. To evaluated fetal presentation and position
- xii. Assessment of liquor amnii
- xiii. Preterm labor/preterm premature rupture of membranes
- xiv. Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retro placenta hemorrhage, abnormal adherence etc.)
- xv. Evaluation of umbilical cord presentation, insertion, nuchal encirclement, number of vessels and presence of true knot
- xvi. Evaluation of previous Caesarean Section scars
- xvii. Evaluation of fetal growth parameters, fetal weight and fetal well being
- xviii. Color flow mapping and duplex Doppler studies
- xix. Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. And their follow-up
- xx. Adjunct diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS) amniocenteses, fetal blood sampling, fetal skin biopsy, amnioinfusion, intrauterine infusion, placement of shunts etc.
- xxi. Observation of intra-partum events
- xxii. Medical/surgical condition complicating pregnancy
- xxiii. Research/scientists studies in recognised institutions
- 11. Procedure carried out (Non-Invasive) Put a "Tick" on the appropriate procedures)
 - i. Ultrasound

(Important Note: Ultrasound is not indicated/advised/performed to determine the sex of fetus except for diagnosis of sex-linked diseases such as Duchene Muscular Dystrophy, Hemophilia A&B etc.)

- ii. Any other (specify)
- 12. Date on which declaration of pregnant women/person was obtained:
- 13. Date on which procedure carried out:....
- 14. Result of the non-invasive procedure carried out (report in brief of the test.....
- 15. The result of pre-natal diagnostic procedures was conveyed to...... On
- 16. Any indication for MTP as per the abnormality detected in the diagnostic procedures/ test.....

Date:

Place:

Name, Signature and Registration Numbers with seal of the Gynaecologist/Radiologist/Registered Medical Practitioner performing Diagnostic procedure/s

Section C: To be filled for performing invasive Procedure/Test only

- 17. Name of the doctor/s performing the procedure/s :
- 18. History of genetic/medical disease in the family (specify).....
 - (a) Clinical (b) Bio-chemical
 - (c) Cytogenetic (d) Other (e.g. radiological, ultrasonography etc. Specify
- 19. Indication for the diagnosis procedure ("Tick" on appropriate indication)
 - A. Previous child/children with:
 - i. Chromosomal disorders
 - ii. Metabolic disorders
 - iii. Congenital anomaly
 - iv. Mental Disability
 - v. Haemoglobinopathy
 - vi. Sex linked disorders

- vii. Single gene disorder
- viii. Any other (specify)
- B. Advanced maternal age (35)
- C. Mother/Father/sibling has genetic (specify)
- D. Other (specify)
- 20. Date on which consent of pregnant women/person was obtained if form G prescribed in PC & PNDT Act, 1994:
- 21. Invasive procedure carried out ("Tick" on appropriate indication/s)
 - i. Chromosomal studies
 - ii. Biochemical studies
 - iii. Molecular Studies
 - iv. Pre-implantation gender diagnosis
 - v. Any other (specify)
- 22. Any complication/s of invasive procedure (specify).....
- 23. Additional test recommended (Please mention if applicable)
 - i. Chromosomal studies
 - ii. Biochemical studies
 - iii. Molecular studies
 - iv. Pre-implantation gender diagnosis
 - v. Any other (specify)
- 24. Result of the Procedures/Test carried out (report in brief of the invasive
- 25. Date on which procedure carried out:....
- 26. The result of pre-natal diagnosis procedure was conveyed to
- 27. Any indication for MTP as per the abnormality detected in the diagnostic procedures tests.....

Date

Place

Name, Signature and Registration Number with Seal of the Gynecologist/ Radiologist/ Registered Medical Practitioner performing Diagnostic Procedure/s

Section D: Declaration

Declaration of the person undergoing prenatal diagnostic test/Procedure

I, Mrs./Mr. declare that by undergoing Prenatal Diagnostic Test/Procedure. I do not want to know the sex of my foetus.

Date

Signature/Thumb impression of the person undergoing the prenatal Diagnostic Test/Procedure

In case of thumb Impression

| Identified by (Name): | Age: | Sex: | ••••• |
|------------------------------------|---------------------------|-------|-------|
| Relation (if any): | Address and Contact No: . | | |
| | | | |
| | | | |
| Signature of person attesting thum | nb impression | Date: | |

Declaration of Doctor/Person Conducting Pre Natal Diagnostic Procedure/Test

Signature.....

Date :

Name in Capitals, Registration Number with Seal of the Gynaecologist/Radiologist/Registration Medical Practitioner Conducting Diagnostic procedure

¹FORM D

[Refer rules 9(2)]

Maintenance of Records by the Genetic Counseling Centre

- 1. Name and address of Genetic Counseling Centre.
- 2. Registration No.
- 3. Patient's Name
- 4. Age
- 5. Husband's/Father Name
- 6. Full address with Tel. No., if any
- 7. Referral by (Full name and address of Doctor (s) with registration no. (s) (Referral note to be preserved carefully with case papers)
- 8. Last menstrual period/weeks of pregnancy
- 9. History of genetic/medical disease in the family (specify)

Basis of diagnosis:

- a. Clinical
- b. Bio-chemical
- c. Cytogenetic
- d. Other (e.g. radiological, ultrasonography
- 10. Indication for pre-natal diagnosis
 - A. Previous child/ children with:
 - i. Chromosomal disorders
 - ii. Metabolic disorders
 - iii. Congenital anomaly
 - iv. Mental retardation
 - v. Haemoglobinopathy
 - vi. Sex linked disorders
 - vii. Single linked disorders
 - viii. Any other (specify)

^{1.} Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003

- B. Advanced maternal age (35 years or above)
- C. Mother/father/sibling having genetic disease (specify)
- D. Others (specify)
- 11. Procedure advised²
 - i. Ultrasound
 - ii. Amniocentesis
 - iii. Chorionic villi biopsy
 - iv. Foetoscopy
 - v. Foetal skin or organ biopsy
 - vi. Cordoecntesis
 - vii. Any other (specify)
- 12. Laboratory test to be carried out
 - i. Chromosomal studies
 - ii. Biochemical studies
 - iii. Molecular studies
 - iv. Preimplatation genetic diagnosis
- 13. Result of diagnosis

If abnormal give details..... Normal/Abnormal

- 14. Was MTP advised?
- 15. Name and address of Genetic Clinic* to which patient is referred.
- 16. Dates of commencement and completion of genetic counseling

Name, Signature and Registration No. of the Medical Geneticist/Gynaecologist/Paediatrician administrating Genetic Counseling

Place:

Date:

^{2.} Strike out whichever is not applicable or necessary

¹FORM E

[Refer rules 9(3)]

Maintenance of Records by the Genetic Laboratory

- 1. Name and address of Genetic Laboratory.
- 2. Registration No.
- 3. Patient's Name
- 4. Age
- 5. Husband's/Father Name
- 6. Full address with Tel. No., if any
- 7. Referral by/sample sent by (Full name and address of Genetic Clinic) (Referral note to be preserved carefully with case papers)
- 8. Type of sample : Maternal blood/Chorionic villus sample/amniotic fluid/Foetal blood or other foetal tissue (specify)
- 9. Specify indication for pre-natal diagnosis
 - A. Previous child/children with
 - i. Chromosomal disorders
 - ii. Metabolic disorders
 - iii. Malformation(s)
 - iv. Mental retardation
 - v. Hereditary hemolytic anemia
 - vi. Sex linked disorder
 - vii. Single disorder
 - viii. Any other (specify)
 - B. Advanced maternal age (35 years or above)
 - C. Mother/father/sibling having genetic disease (specify)
 - D. Other specify

^{1.} Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003

- 10. Laboratory test carried out (give details)
 - i. Chromosomal studies
 - ii. Biochemical studies
 - iii. Molecular studies

iv. Preimplantation genetic diagnosis

11. Result of diagnosis

If abnormal give details.

12. Date (s) on which test carried out.

Name, Signature and Registration No. of the Medical Geneticist/Director of the Institute

Place:

Date:

¹FORM G

[Refer rule 10] Consent (For invasive techniques)

| I,Wife/ | daughter of | Age | |
|---------------------------------|---------------------------|------------------------------------|-----|
| years residing at | hereby state | e that I have been explained fully | the |
| probable side effects and after | r effects of the pre- nat | tal diagnostic procedures. | |

I, wish to undergo the preimplantation/pre-natal diagnostic technique/test/procedures in my own interest to find out the possibility of any abnormality (i.e. disease/deformity/ disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure/technique/test conducted show the absence of disease/deformity/disorder.

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 Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)¹ and rules framed there under.

Signature of the pregnant women

Place:

Date:

| I have explained | the contents of the above to the | e patient and her companion | |
|--------------------------------------|----------------------------------|-----------------------------|--|
| (Name Relationship | | | |
|) in a language she/they understand. | | | |

Name, Signature and Registration Number of Gynaecologist/Medical Geneticist Radiologist/Paediatrician/Director of the Clinic/Centre Laboratory

Date :

Name, Address and Registration number of Genetic Clinic/ Institute

SEAL

^{1.} Now "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"

Sample format of Show Cause Notice under Section 20(1) Name and address of the Appropriate Authority sending the notice

Name of the person/centre

Address

Subject: Show cause notice under Section 20(i) of PCPNDT Act, 1994

- 1. Whereas the undersigned is an Appropriate Authority under the PCPNDT Act and vide order no..... dated.... is duly authorised and competent to cancel or suspend the registration of (Name of the Centre and the owner) under the aforesaid Act.
- 2. Whereas the Appropriate Authority has observed the following violations at your centre during the inspection carried out on this____ date at time ___ under the different provisions of PCPNDT Act and rules framed thereunder:
 - i)
 - ii)
 - iii)
 - iv)
 - v)
- 3. In view of the aforesaid, you are hereby called upon to show cause as to why the registration no......issued ondate......date......to (Name of the Owner and Centre) should not be cancelled/ suspended for the reasons mentioned herein above.
- 4. You are hereby directed to reply to the said notice, along with all documents relied upon by you in the reply, within 7 days from the date of the receipt of this notice.
- 5. In case no reply to this show case notice is received by the Appropriate Authority within the stipulated time at the address of the Appropriate Authority mentioned herein above, it shall be presumed that you have admitted the allegations made in this notice and the Appropriate Authority will proceed accordingly.

Notified Accordingly

Appropriate Authority under PCPNDT Act/or officer so authorised.

Place

Date

Guidelines for Search and Seizure Operations

It has come to this Ministry's notice that the Appropriate Authorities make a number of errors while carrying out an investigation at a facility. Investigation shall be done and necessary action shall be taken on erring facilities as per the Rules given below for the confiscation of machines, papers and sealing of the machine and the centre.

RULES AS PER Section 30 (1) AND RULE 12 IN THE PRE CONCEPTION AND PRE NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994, Rules 1996

- 1. The Appropriate Authority or the officer so authorised by such Appropriate Authority shall have the right to investigate and seize as per Section 30 (1) of the Pre Conception and Pre Natal Diagnostic Techniques Act
- 2. The Appropriate Authorities or the officers so authorised on behalf of Appropriate Authorities shall have right to inspect and carry search and seizure under Pre Conception and Pre Natal Diagnostic Techniques Act as per Rule 12
- 3. The Appropriate Authorities or officers so authorised may seek assistance for inspection and search and seize operations
- 4. The Appropriate Authorities and the officers so authorised may visit any facility at all reasonable times and carry out inspection and search and seizure
- 5. The Appropriate Authorities and the officers appointed by them shall have the right to seize and seal all documents, registers, books, advertisements and all other related material present at the centre or place where the violation is found to have taken place
- 6. The Appropriate Authorities and the officers so authorised shall have the right to demand all documents and other information at the centre from the owner of the centre or any other person available there
- 7. It shall be mandatory for the owner of the facility or the person present there to provide all the information demanded by the Appropriate Authorities and the officers so authorised
- 8. Presence of not less than two independent witnesses shall be mandatory at the time of making the *Panchnama* depending on the availability of witnesses
- 9. It shall be mandatory to make the *Panchnama* at the centre in the presence of the *Panchas*.
- 10. It shall be mandatory to make an inventory of the seized documents and the Sonography machine at the time of making the *Panchnama* along with the site plan

- 11. It shall be mandatory to make the inventory of the seized equipment/machine and the documents in the presence of the witnesses and the owner/employee of the centre
- 12. Two witnesses are required if available and owner/employee of the facility to sign on the *Panchnama*
- 13. Appropriate Authorities/Authorised officer should mandatorily carry for inspection/ search/seizure necessary items such as thread, lacquer (*lakh*), white cotton cloth, government seal, rubber stamp, lock and key etc.
- 14. After a thorough inspection of the facility, all the papers and documents so seized and sealed should be taken into custody immediately then and there
- 15. All machines/equipment found in the premises should be sealed and seized and taken into custody. After the *panchnama* is made, the owner/employee of the centre shall be informed that the machine/equipment is henceforth the property of the government and shall be left with him/her for preservation on a declaration and an acknowledgement receipt shall be taken from owner/employee
- 16. The entire premises shall be inspected, including the house, hospital and garage. There is always a possibility that an unregistered machine is on the premises
- 17. All items including Registration Certificate (issued in duplicate), board, F Form, including the declaration of the pregnant woman, declaration of the doctor, OPD register, birth register or any other register, copies of the Act, referral slips, documents related to registration, documents related to the equipment/machine or other relevant documents such as bills/receipts etc. should be taken into custody.

Note attachments with these guidelines:

- Sample format for seize and seal Panchnama
- Sample format for cancellation/suspension of registration

THE SAMPLE FORMAT OF SEIZE AND SEAL PANCHNAMA

Today, Date & time on the inspection of the facility of (name of owner/facility/address) under the provisions of the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994 the following articles were seized be invigorative of the PCPNDT Act & Rules thereunder

Since lapses have been found as mentioned above, the following items have been seized. The seizure as well the Panchnama has been made in the presence of *panchas* (not less than two independent witnesses)

In the presence of

| 1. | |
|----|--|
| 2. | |
| 3. | |
| 4. | |
| 5. | |
| 6. | |
| | |

Owner/employee of the Facility

Appropriate Authority

Authorised officer

1)

2)....

| Witnesses:- | |
|-------------|--|
|-------------|--|

| 1) | | | |
|----|--|--|--|
| 2) | | | |
| 3) | | | |
| 4) | | | |

INDICATIVE FORMAT OF ORDER FOR SUSPENSION/CANCELLATION OF REGISTRATION OF THE FACILITY UNDER THE PCPNDT ACT, SECTION (20)

| Order | Date |
|--|---|
| Subject:- Regarding Cancellation / Suspens | sion of Registration |
| Ref: | |
| On Datean inspection of | of the facility of |
| | e/owner/address) as per the provisions of the |
| Pre-Conception and Pre-Natal Diagnostic | Techniques (PCPNDT) Act, 1994, was carried |
| out | (Name of Appropriate Authority/Authorised |
| officer). Following lapses have been found | at the facility. |

Facts and Narration of the lapses

| 1) | |
|----|--|
| 2) | |
| | |
| | |
| 5) | |
| 6) | |

OR

| As per Clause 20 (3) of the Pre-conception and Prenatal Diagnostic Techniques |
|---|
| (Prohibition of Sex Selection) Act, 1994, on account of public interest |
| (reason) the |
| registration of your facility has been suspended until further notice. |

Note:-

- This order shall be treated as the sample for cancellation / suspension of registration and the blank spaces should be filled accordingly.
- The relevant Sections and Rules of the Act shall be followed carefully during search and seizure of the facility and a corresponding report shall be submitted.

Name and signature of Appropriate Authority

To,

(Name of facility and owner)

Annex 13

Sample Format of a Complaint to be Filed in the Court of Judicial Magistrate First Class AT____ COMPLAINT CASE NO.____/2011

In the matter of: DR/Shri.....) APPROPRIATE AUTHORITY/MEDICAL OFFICER, Hospital)

| Through authorised representative | |
|---|-------------------------|
| ADDRESS) | COMPLAINANT |
| VERSUS | |
| Name of the accused in whose name licen | ise is issued |
| In case of company, company name and p | erson guilty of offence |
| ADDRESS | |
| |) |
| |) |
| |)ACCUSED |

Complaint under Sections200 CRPC Read with PCPNDT ACT

Nature of the case: (brief background provided by AA) Facts of the case Offences committed

Details of evidence collected

List of documents filed

List of witnesses

- I, (Name and designation)being the Appropriate Authority or officer so authorised vide order no.....being the under the Pre-Conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.
- 2. While implementing PCPNDT Act I found¹.....

A. (Date wise events, time, place, names of individuals with address)

В.....

C.....

- 4. Recorded the statement of the accused Name_____

CONTRAVENTION OF THE ACT WAS FOUND AS FOLLOWS:

- 1. 2. 3. 4. 5. 6. 7. 8.
- 9.

Note: Indicative Sections and Rules applicable for following violations

- Pregnant woman was informed of the sex of the foetus. Section 5(2)
- No copy of the PC and PNDT ACT and Rules framed thereunder was found at the Ultrasonography Centre. Rule 17 (2)
- Form F not submitted. Section 19, Rule 9 (4)
- Doctor had not signed the undertaking. Rule 10 (1-A)
- No consent obtained from the pregnant woman. Section 5 (b)
- Report not submitted to Appropriate Authorities in time. Rule 9 (8)

¹ Note: Please narrate facts clearly

- Unregistered person was found performing Ultrasonography Section 3(3)
- Referral slip was not maintained. Rule 9(4)
- Records required by the Act were not maintained. Section 29 (1)

Rule - 9

The accused_(Name) ______has been found to have contravened the provisions of the Act. I pray that the accused_(Name) _______should be punished as per Sections 23, 25, 26, of the PC and PNDT Act and Rules.

LIST OF WITNESSES

| L | |
|---|-------|
| | |
| 2 | |
| | ••••• |
| | |
| 3 | |

| Place : | Sd/- |
|---------|------------------------|
| Date : | Appropriate Authority |
| | /officer so authorised |

(Seal)

Note: List of documents serving as evidence on which complaint is based should be attached properly with the complaint. All documents to be attached in original.

Annex 14

Sample Format for Undertaking from Pregnant Woman Acting as Decoy (To be translated in local language and explained to pregnant woman in a language she understands)

I,______Age____years, residing at______ hereby state that I am a resident of the address mentioned above and am ______months pregnant. I am ready to act as a Decoy client in order to help in implementation of the PCPNDT Act to prevent sex determination.

My future child is precious to me whether it is a son or a daughter. Under no circumstances will I undergo a sex selective abortion, if the sex if the foetus is revealed to me during the course of the decoy operation.

I am giving this undertaking with my free will in order to be of help in implementation of the Pre-conception and Prenatal Diagnostic Techniques Act. I will attend Court proceedings regularly and willingly.

The details of the currency notes given to me to pay to the doctor in order to help in implementation of the PCPNDT Act are as follows

| S. No | Serial Number on the Note | Denomination of Note |
|-------|---------------------------|----------------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| | Total Amount Paid | |

Place:

Date:

Time:

Signature of the woman writing the undertaking

Signature of witnesses

| 1. | Name: | Signature: |
|----|-------|------------|
| 2. | Name: | Signature: |

Declaration of pregnant woman's/decoy's relative:

I Husband/ Mother in Law/ Mother/ Brother/ Any other (please specify) of who has agreed to act as a decoy client have no objection for her role as a decoy that would help in effective implementation of the PCPNDT Act.

Place:

Date:

Signature of the relative of the decoy client

Annex 15

Sample Format of Panchnama Concerning a Decoy Operation (To be filled in if the decoy operation was successful)

Separate seizure memo shall be prepared of each and every article seized, being the relevant evidence of the case and each has to be proved separately

On (date) // Time AM/PM in Taluka/district_____(specify Address), I Appropriate Authority, Shri / Smt......Name, (Designation) Medical Officer Of Health Centre / Hospital in Taluka...... District in a legal action taken as per the provisions of PCPNDT ACT 1994, in the presence of the following Panchas (There should be no less than two Panchas for the Panchanama, if possible)

| 1. | Names | Address |
|----|-------|----------|
| 2. | Names | Address |
| 3. | Names | _Address |
| 4. | Names | Address |
| 5. | Names | Address |

seized the following documents, files, registers, cash, other material, machine/equipment, etc.

1. Total amount paid by the patient - Rupees./- (provide details below)

| S. No | Serial Number on the Note | Denomination of Note |
|-------|---------------------------|----------------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| | Total Amount | |

| 2. | Register as per Rule 9(1):Nos. |
|----|---|
| | Beginning with patientending with patient |
| | From dateto dateto |

- 3. Other Registers and documents (Please specify)
 - xxx
 - xxx
 - xxx
- 4. Registration Certificate (seize both copies)

Valid from Date to

- 5. Ultrasonography Machines/ Equipment: Type.....Nos.....Nos.
 - Name of the Manufacturer _____ Model No._____
 - Name of the Manufacturer _____ Model No._____
 - Name of the Manufacturer _____ Model No._____
- 6. Total No of Probe._____
 - Serial No on Probe 1.....
 - Serial No on Probe 2.....
 - Serial No on Probe 3.....
- 7. Computer, laptop and any other equipment linked to the machine/equipment (provide details)

| All the items as listed above were taken into custody on date |
|---|
| and the acknowledgment of the same was given to the concerned doctor (Specify |
| Name) |

| Place: | |
|--------|--|
| | |

| Date: | |
|-------|--|
| | |

Time: _____

Signature of Panchas

| 1. | Names | _address | _Signature |
|----|-------|----------|------------|
| 2. | Names | _address | _Signature |
| 3. | Names | _address | _Signature |
| 4. | Names | _address | _Signature |
| | | | |

5. Names______address______Signature

In the presence of Appropriate Authority or the officer so authorised (specify name) _______of Hospital (Specify name), ______(Name of doctor) received acknowledgment of the items seized.

Date: _____

Signature of accused: _____ Name: _____

Time: _____

Address: _____

Annex 16

Guidelines for Conducting a Decoy Operation

As per the Census 2011, the child sex ratio of the country in the age group 0-6 years declined dramatically to 918girls per 1000 boys as compared to 927 in 2001. Efforts are on to prevent gender biased sex selection through various measures including, the effective implementation of the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994. Under the provisions of this Act, the District Civil Surgeon and Medical Officers or the District Magistrate are appointed as the Appropriate Authorities for the district and it is their responsibility to effectively implement the Act in their area of work.

While implementing the PCPNDT Act, the Appropriate Authorities may send decoy cases/ pregnant women to concerned facilities or centres that are suspected to be violating the PCPNDT Act, to carry out a decoy operation at such centres. The guidelines for carrying out such decoy operations in suspected centres are given below:

- 1. A woman who is 14 to 22 weeks pregnant may be selected as a decoy case and after counselling her, she may be trained to participate in the decoy operation
- 2. Two witnesses may be selected and sent along with the identified decoy client/ pregnant woman
- 3. An affidavit/undertaking as per Annex 14 stating that she is willing to participate as a decoy case may be obtained from her. The serial numbers of the notes that are going to be used in the sting operation may be mentioned in the said affidavit/undertaking. These currency notes may be given to the woman or the witnesses and they may be instructed to use the same notes in the decoy operation
- 4. To gather evidence, they may be given with them, hidden audio and video recorders. The team participating in this decoy operation may be trained efficiently to handle the equipment so as to avoid any confusion. The audio and video recording would prove to be strong evidence in the court of law and help punish the persons violating the law
- 5. Appropriate Authorities/Authorised officer may be present near the centre where the decoy operation is being carried out to take swift action when required
- 6. If they feel, AA and the team may keep the phone numbers of the nearby police station handy and may not hesitate to take help of the police if necessary
- 7. As soon as the Appropriate Authorities come to know that the decoy operation is successful, they may keep the concerned owner, staff, employees of the clinic under constant observation and make sure that his or her phones are switched off so that he/ she does not contact anybody

- 8. Currency notes may be confiscated after a *Panchnama* from the accused and the numbers on them may be crosschecked and confirmed with the notes used in the decoy operation
- 9. A thorough enquiry may be made and a statement may be obtained from the accused as well as the co-accused (Paramedical staff, agent, P.R.O.)
- 10. After a thorough inspection of the centre, all the documents may be seized as per the rules and the centre may be sealed
- 11. Equipment/ machines may be seized and sealed. After conducting a *Panchnama* and seizure of the machine and papers, acknowledgement receipt of the same may be given to the accused, signed by both parties
- 12. The video camera may be kept running while the inspection is being made
- 13. The entire premises of the hospital may be checked and inspected. There is always a possibility that an unregistered machine is in operation. If so, such a machine/ equipment must be seized and sealed
- 14. Papers including Registration Certificate (both copies), Board, F Form, Declaration of the pregnant woman, Declaration of the doctor, OPD register, Birth register, reference slips, papers concerning registration, papers concerning the Sonography machine, etc. may be seized
- 15. Testimonies and statements of the woman and the witnesses may be recorded on the location and papers, audio and video recording equipment; cassettes, etc. may be obtained from them. The woman and the witnesses may be given copies of their statements and cassettes
- 16. Investigation Report may be prepared there right after the investigation is done.

Annex 17

Indicative Checklist to Ascertain Completeness of Legal Documentation Filing of a Case under the PCPNDT Act

| Sr. | Legal Issue and Document | PCPNDT Act- Sections |
|-----|--|-----------------------|
| No | | and rules |
| I | Technical | |
| 1 | Notification of Appropriate Authority | S.28(a), Section 7(1) |
| 2 | Appointment Letter/authorisation letter by the AA in | |
| | case inspection is carried out by officer authorised by AA | |
| 3 | Power Delegation Letter | |
| 4 | Statements- Witnesses | C. R. P. C |
| 5 | Inspection Report | S. 20(a) |
| 6 | Show cause Notice issued by the AA | |
| 7 | Notice of Advisory Committee meeting | S. 17 (4) (c) |
| 8 | Copy of recommendations of Advisory Committee | S. 20 |
| 9 | Copy of the Answer received from the accused/ | |
| | confession of accused if obtained | |
| 10 | Order of Cancellation/suspension of registration Order | S. 20 |
| П | Panchanama | |
| 1 | Documents | |
| | a) Register | R. 9 (1)(4) |
| | b) OPD Register | |
| | c) Consent Register | S.5, R.10(2) |
| | d) Declaration Register | R. 10 (1-A) |
| | f) Referral Slips | S.29, R.9 (4) |
| | g) Birth registration register | |
| | h) Ultra Sonography Reports Registration | S.29 |
| | i)Monthly reporting file to Appropriate Authority | R. 9 (8) |
| | j) Photo of Board displaying that sex selection is illegal | R. 17 (1) |
| | and not done at the centre/clinic. | |
| | k) Copy of the Book of the Act | R. 17(2) |
| | I) Money and receipts | |
| | m) Printout of computer records | |

| Sr. No | Legal Issue and Document | PCPNDT Act- Sections and rules |
|-----------|--|-----------------------------------|
| 2 | Sonography Machine | S.30 – R.12- Search & Seize |
| | a) Probe | |
| | b) Computer, including memory chip | |
| | c) C.C.TV & Recorder (along with transcription of the recording) | |
| | d) Currency notes if seized | |
| | e) Quotation File | |
| | f) Purchase File | |
| | g) Registration correspondence File | S. 18 , R.6(1) |
| | h) Registration Cetificates-2 Copies-Original | S. 19 (4), R.6(2) |
| 3 | Statement of Witness | C.R.P.C |
| | 1)Panchnama- original | |
| | 2)one of the Panch is Gov. servant | |
| | 3) Whether the Panchnama is in Format | |
| Ш | Statements | |
| 1 | Decoy Affidavit/undertaking | |
| 2 | Decoy statement | |
| 3 | Statement of witness | |
| 4 | Others specify | |
| 5 | Others specify | |
| 6 | Statement of the accused | |
| 7 | Confession Letter of the accused | |
| 8 | Statement of the paramedical staff | |

Note: All documents to be submitted in original

Annex 18

General Provisions of the Code of Criminal Procedure Regarding Search and Seizure Operations

Following are general provisions provided under Code of Criminal Procedure 1973:

S. 100. Persons in charge of closed place to allow search-

- 1. Whenever any place liable to search or inspection under this Chapter is closed, any person residing in, or being in charge of, such place, shall, on demand of the officer or other person executing the warrant, and on production of the warrant, allow him free entrance thereto, and afford all reasonable facilities for a search therein
- 2. If entrance into such place cannot be so obtained, the officer or other person executing the warrant may proceed in the manner provided by sub- section (2) of section 47. Sec 47(2) : If ingress to such place cannot be obtained under subsection (1), it shall be lawful in any case for a person acting under a warrant and in any case in which a warrant may issue, but cannot be obtained without affording the person to be arrested an opportunity of escape, for a police officer to enter such place and search therein, and in order to effect an entrance into such place, to break open any outer or inner door or window of any house or place, whether that of the person to be arrested or of any other person, if after notification of his authority and purpose, and demand of admittance duly made, he cannot otherwise obtain admittance: Provided that, if any such place is an apartment in the actual occupancy of a female (not being the person to be arrested) who, according to custom, does not appear in public, such person or police officer shall, before entering such apartment, give notice to such female that she is at liberty to withdraw and shall afford her every reasonable facility for withdrawing, and may then break open the apartment and enter it
- 3. Where any person in or about such place is reasonably suspected of concealing about his person any article for which search should be made, such person may be searched and if such person is woman, the search shall be made by another woman with strict regard to decency
- 4. Before making search, the officer or other person about to make it shall call upon two or more independent and respectable inhabitants of the locality in which the place to be searched is situate or of any other locality if no such inhabitant of the said locality is available or is willing to be a witness to the search, to attend and witness the search and may issue an order in writing to them or any of them so to do

- 5. The search shall be made in their presence, and a list of all things seized in the course of such search and of the places in which they are respectively found shall be prepared by such officer or other person and signed by such witnesses, but no person witnessing a search under this section shall be required to attend the Court as witness of the search unless specially summoned by it
- 6. The occupant of the place searched, or some person in his behalf, shall, in every instance, be permitted to attend during the search, and a copy of the list prepared under this section, signed by the said witnesses, shall be delivered to such occupant or person
- 7. When any person is searched under sub- section (3), a list of all things taken possession of, shall be prepared, and a copy there of shall be delivered to such person
- 8. Any person who, without reasonable cause, refuses or neglects to attend and witness a search under this section, when called upon to do so by an order in writing delivered or tendered to him, shall he deemed to have committed an offence under section 187 of the Indian Penal Code (45 of 1860).

Relevant Provisions of Criminal Procedure Code with Respect to Seizure of the Property Suspected to be involved in the Commission of an Offence

Section 102 Criminal procedure code: Power of the police officer to seize property

- 1. Any police officer may seize any property which may be alleged or suspected to have been stolen or which may be found under the circumstances, which create suspicion of commission of offence
- 2. Such police office, if subordinate to the officer in charge of the police station shall forthwith report that seizure to that officer
- 3. Every police officer acting under sub section 1 shall forthwith report the seizure to the magistrate having jurisdiction and where the property seized is such that it cannot be conveniently transported to the court or where there is difficulty in securing proper accommodation for the custody of the said property or where the continued retention of the property may not be considered necessary for the purpose of investigation he may give custody to any person on his executing a Bond undertaking to produce the property before the court as and when required and to give effect to the further orders of the court as to the disposal of the same.

Provided that where the property seized under sub section 1 is subject to speedy and natural decay and if the person entitled to such possession is unknown or absent and the value of the property is less than 500 Rupees it may forth with be sold by auction under the orders of SP and the provision of 457 and 458 may be applicable apply to the net proceeds of such sale.

Section 451 of criminal procedure Code:

Order for custody and disposal of property pending trial in certain cases – when any property is produced before the criminal court during any inquiry and trial, the court may make such order as it think fit for the proper custody of such property pending the conclusion of inquiry or trial and if the property is subject to speedy and natural decay, or if it otherwise expedient to do so, the court may, after recording such evidence as it think necessary, order it to be sold or otherwise disposed off.

Explanation: for the purpose of this section property includes:

- a. Property of any kind or document which is produced before the court or which is in its custody
- b. Any property regarding which an offence appears to have been committed or which appears to have been used
- 4. Section 457 Criminal Procedure code: whenever the seizure of the property by the police officer is reported to a magistrate under the provision of this Code and such property is not produced before a criminal court during an enquiry or that the magistrate may make such order as he thinks fit respecting the disposal of such property or the delivery of such property to the person entitled to the possession thereof or if such person cannot be ascertained, respecting the custody and production of such property

If the person so entitled is known, magistrate may order the property to be delivered to him on such condition (if any) as the magistrate may think fit and if such person id unknown the magistrate may detain, it and shall in such case issue a proclamation specifying the articles of which such property consists and requiring any person who may have a claim thereto, to appear before him and establish his claim within six months from the date of such proclamation.

Note: For the Purpose of PC&PNDT Act, Appropriate Authority has been given all the powers similar to that of a police officer as per the section 17 A (for search and seizure) and shall be acting in compliance with the provisions of CrPC

Section II: PCPNDT Act related Advisories issued by the Ministry of Health and Family Welfare, Government of India

Appointment of District Magistrate as District Appropriate Authority [12 February 2007]

No. 24026/III/06-PNDT Ministry of Health & Family Welfare Government of India

> Nirman Bhawan, New Delhi Dated :- 12TH Feb, 2007

OFFICE MEMORENDUM

Under Section 17(2) of the Pre Conception & Pre-Natal Diagnostic Techniques Act, 1994 amended in 2002, State Govt. shall appoint, by notification in the Official Gazette one or more Appropriate Authorities for the whole or part of the State for the purpose of the Act having regard to the intensity of the problem of pre-natal sex determination leading to female Foeticide. The Central Supervisory Board, constituted under the Act, in its 15th meeting held on 09th January, 2007 under the Chairmanship of Union Minister of Health & Family Welfare has decided that District Appropriate Authority shall be the District Magistrate (DM) for the District. The DM may nominate an executive magistrate of the district as his/her nominee to assist him/her in monitoring the implementation of the PC & PNDT Act, as deemed necessary.

All State Governments are requested to issue necessary notification to implement the decision with immediate effect.

Jushma

(Sushma Rath) Under Secretary to the Govt. of India

Secretary (H&FW) Al! States/UTs

Copy to:-Ms. Ena Singh, UNFPA.

Registration of a ultrasound clinic by a gynaecologist [16 August 2012]



1 speedpah

Nirman Bhawan, New Delhi Dated, the 16, August, 2012

Subject: Registration of Ultrasound Clinic by Gynaecologist- reg.

Sir/Madam,

Ministry of Health and Family Welfare has received a number of representations seeking clarification whether Gynaecologists are qualified under the PC & PNDT Act to conduct ultrasound procedures. In this regard, it is clarified that a medical practitioner with post graduation in Gynaecology and Obstetrics is qualified as per the PC & PNDT Act and the Rules framed therein to conduct ultrasound in a Genetic Clinic/ Ultrasound Clinic/Imaging Centre.

You are requested to disseminate the clarification above to the concerned Appropriate Authorities under the PC & PNDT Act at State/district level.

Yours faithfully

(Manoj Jhalani)

Joint Secretary

Copy to:

- 1. Mission Director, NRHM (All States/UTs)
- 2. State Appropriate Authority
- President, The Federation of Obstetrics and Gynaecological Societies of India (FOGSI), Mumbai.

Clarification regarding qualification of registered medical practitioner having Diploma in Gynaecology and Obstetrics [19 November 2013]

No. F.12011/56/2012-PNDT Government of India Ministry of Health and Family Welfare (PNDT - Section)

Nirman Bhawan, New Delhi Dated 19th November, 2013

То

The Principal Secretaries, (Health & Family Welfare Department), All States/UTs.

Subject: - Clarification regarding qualification of registered medical practitioner having Diploma in Gynaecology and Obstetrics (DGO).

Madam/Sir,

I am directed to refer to this Ministry's letter No. N.24026/52/2008-PNDT dated 16.08.2012 and to say that in many States, various authorities under the PC&PNDT Act, 1994 are giving restrictive interpretation regarding qualification of Gynaecologist and that a number of representations have been received in this Ministry against such restrictive interpretation. It is further observed that no efforts have been made by such authorities to seek clarification, if any such doubt occurs, before issuing letters/notifications based on such restrictive interpretation of the provisions of the Act/Rules.

2. In this context, reference is invited to the provisions contained in Rule 3(3)(1)(b) of the PC&PNDT Rules, 1996 which *inter alia* stipulates that a Registered Medical Practitioner having Post Graduate degree or diploma is qualified to set up an ultrasound clinic or being employed in an ultrasound clinic.

3. It is, accordingly, clarified that Diploma in Gynaecology and Obstetrics (DGO) is a post graduate qualification and hence a registered medical practitioner having Diploma in Gynaecology and Obstetrics (DGO) is qualified to set up or being employed in an ultrasound centre within the meaning and scope of PC & PNDT Act, 1994 and the Rules framed thereunder.

 Contents of this letter may be disseminated to all concerned for information and compliance.

This issues with the approval of the competent authority.

Yours faithfully,

Dha

(D.N. Sahoo) Under Secretary to the Government of India Tel/Fax : 011- 23061875

Copy to:-

The Nodal Officer PNDT, All States/ UTs

Clarification regarding DMRE degree – Diploma in Medical Radiology and Electrology/ Electrotherapy [9 August 2014]

Speed fort

No. F. 12011/10/2014-PNDT Government of India Ministry of Health & Family Welfare (PNDT Section)

Nirman Bhawan, New Delhi, Dated the 19 August, 2014

Dr. Suresh Seth Head of Office Directorate of Family Welfare Govt. of Delhi Vikas Bhawan II, 7th Floor, B- Wing Civil Line, New Delhi- 110054

Subject: Clarification regarding DMRE degree - reg.

Sir,

66759/14

To,

With reference to you letter no. F.9(7)9/PNDT/DFW/14-15/ 6974, dated-31/07/2014 and e-mail dated- 23rd July 2014, it is to submit that as per the provision under the PC & PNDT Act and Rules framed thereunder, MD (Radiology), DNB & Post Graduate Diploma in Medical Radio diagnosis are the MCI recognised courses under Radio-diagnosis and have also been recognised as credentials to grant registration/ renewal under PC & PNDT Act/ Rules. Diploma in Medical Radiology and Electrology/ Electrotherapy (DMRE) does not qualify for registration/ renewal granted as per the provision of the Act.

Therefore, you may like to take further course of action as per the extant provisions of the PC & PNDT Act, 1994 & PC & PNDT Rules, 1996 amended from time to time.

Yours faithfully,

OC

(Dr. R. P. Meena) (4/8/2014 Director (PNDT) Tel: 23063628

Copy to-

66762/14

State Appropriate Authority, Delhi Directorate of Family Welfare Govt. of Delhi, Vikas Bhawan II, 7th Floor, B- Wing Civil Line, New Delhi- 110054

Registration of IVF/ART centres/clinics under the PCPNDT Act, 1994 [9 October 2014]

Speed part Veuse 19. F. No.12011/25/2014-PNDT Government of India Ministry of Health & Family Welfare (PNDT Section) Nirman Bhawan, New Delhi Dated the October, 2014 To, The Chairperson State Appropriate Authority

Subject: Registration of IVF/ART Centres/Clinics under PC&PNDT Act, 1994 – Issuance of guidelines reg.

Sir/Madam,

All States/UTs

I am directed to state that all ART/IVF procedures/tests & techniques are recognized as pre-natal diagnostic procedures/ pre-natal diagnostic techniques/ pre-natal diagnostic tests or under Sections 2(i), 2(j) and 2(k) of the PC&PNDT Act 1994, which are reproduced as under:

Section 2(i) "prenatal diagnostic procedures" mean all gynaecological or obstetrical or medical procedure such as ultrasonography, foetoscopy, taking, 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, or 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.

Section 2(j) "prenatal diagnostic techniques" include all pre-natal diagnostic procedures and pre-natal diagnostic tests.

Section 2(k) "pre-natal diagnostic test" means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, embryo, blood or any other 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.

2. In view of the above provisions of the Act, all the ART clinics or centres/IVF clinics or centres/Surrogacy Clinics or centres or other such centres are mandatorily required to be registered under PC&PNDT Act 1994 either as Genetic Counselling Centres [Section 2(c)], Genetic clinics [Section 2(d)] or Genetic Laboratories [Section 2(e)], as defined under the PC&PNDT Act 1994 depending on the activities being performed by the centres/clinics.

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3. Further, the range of activities of these centres/clinics or laboratories is extensively defined under Sections 2(i), 2(j) and 2(k) of the PCPNDT Act 1994. All diagnostic procedures/techniques/tests conducted in such clinics/centres should be recorded either in the Form F (revised) or Form E (whichever is relevant) and reported to the Appropriate Authorities concerned. Sections A, B, C of the revised Form F capture all possible diagnostic procedures/tests, non-invasive diagnostic procedures/tests and invasive procedures/tests. Point 21(v) of Section (C) of revised Form F may capture any other invasive procedures/tests if it is not explicitly covered under the revised Form F.

4. As such, there is no need of a separate Form F for the IVF/ART centres and the IVF/ART centres are mandatorily required to be registered under the PCPNDT Act 1994. All the Appropriate Authorities concerned are advised to compile and update data related to such ART/IVF centres as a part of QPR and submit accordingly to this Ministry as clearly required under Rule 9(8) of the PC&PNDT Act 1996.

6. This issues with the approval of competent authority.

Kindly acknowledge the receipt of this letter

Yours faithfully,

(Dr.R.P.Meena) aoly Director (PNDT) Tel: 23063628

Copy to: Nodal Officers (PNDT) of all States/UTs.

Clarification regarding use of portable ultrasound machines/portability of ultrasound machines [9 October 2014]

Speed Rest

No. F.12011/32/2014-PNDT Government of India ministry of Health & Family Welfare (PNDT Section)

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Nirman Bhawan, New Delhi Dated the 9th October, 2014.

The Chairperson State Appropriate Authorities, All States/UTs

Subject: Clarification regarding the use of portable ultrasound machines/ portability of ultrasound machines - reg.

Sir/ Madam,

Various representations have been received in this Ministry seeking clarification on the use of portable ultrasound machines. The issue was examined in the Ministry and the following is stated in this regard:-

- (i) As per Rule 3B (1) of the PC & PNDT Rules, 1996, the use of portable ultrasound machine or any other portable machine or device which has the potential for selection of sex before conception or detection of sex during pregnancy shall be permitted only in the following <u>conditions; namely-</u>
 - (a) <u>The portable machines being used</u>, within the premises it is registered for providing services to the indoor patients and
 - (b) <u>As a part of a mobile medical unit offering a bouquet of other health and medical services;</u>
- (ii) For the purpose of this sub-rule, it is explained in the Explanation that the expression, "other health and medical services" means a host of services provided by the mobile medical unit which include curative, reproductive and child health services, family planning services, diagnostic investigation, specialized facilities & services and emergency services as specified under Explanation from (i) to (vi) under Rule 3B (1).

2. With regard to regulation of services to be offered by mobile Genetic Clinic under Rule 3B (2), the following have been prescribed –

(a) A Mobile Genetic Clinic shall operate and offer pre-natal diagnostic techniques, only as part of a Mobile Medical Unit offering a bouquet of

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other health and medical services in urban slums or rural or remote or hilly or hard to reach areas for improved access to health care services by under-served populations.

- (b) The machine under no circumstances shall be used for sex determination of the foetus.
- (c) The stand alone mobile ultrasound clinics offering only pre-natal diagnostic facilities are prohibited.
- (d) The mobile unit offering diagnostic services shall have adequate space for providing the facilities to patients.

3. A close reading of the provisions of Rule 3B (1) and 3B (2) of the PC & PNDT Rules, 1996, clearly reveals that there is no ambiguity in the rules needing further clarification.

4. It is therefore reiterated that portable machines/portability of ultrasound machines are banned except under the circumstances specified above.

5. This issues with the approval of the Competent Authority. The contents of this letter may be brought to the notice of all concerned for compliance.

Yours faithfully,

(Dr.R.P.Meena)9/10/ 2019 Director (PNDT) Tel: 011-23063628

Copy to:- Nodal Officers (PNDT) of all States/UTs.

Medical audit of all records including Form F under the PCPNDT Act, 1994 [12 May 2015]

No. N.24026/06/2015 - PNDT Government of India Ministry of Health & Family Welfare (PNDT Division)

> Nirman Bhawan, New Delhi Dated the 12th May, 2015

To,

The Principal Secretaries (Health & FW), All States/UTs,

Subject:-

the PC & PNDT Act, 1994 - reg.

Sir/Madam,

I am directed to recall that the records have to be maintained and preserved in the prescribed formats under as per the PC&PNDT Act, 1994 and rules framed thereunder by the Genetic Counselling Centres/Genetic Clinics/Genetic Laboratories/Ultrasound Centres/Imaging Centres etc.

2. In this regard in the Central Supervisory Board [constituted under the Preconception and Pre-natal Diagnostics Techniques Act (PC & PNDT Act), 1994] in its 22nd Meeting of held on 13th October, 2014 under the Chairmanship of Hon'ble HFM, has noticed that the scrutiny/ Examination of various record is not being done properly by the concerned appropriate authorities.

3. The CSB has directed to conduct medical audit of all records including Form F, E, D and G by the District Appropriate Authorities. It is therefore, requested to instruct the District Appropriate Authorities to scrutinize and analyse all records to be maintained under the PC & PNDT Act, 1994 and rules as it would help the Appropriate Authorities to identify the actual culprits who are involved in the illegal practice of sex selection. Further, the authorities may also analyse all records, including OPD, IPD and outcome registers of the IVF centres/facilities.

Yours faithfully,

Clarification regarding the powers of State Appropriate Authority and closure of unused/idle/surrendered ultrasound machines [12 May 2015]

No. V.11011/05/2013 - PNDT Government of India Ministry of Health & Family Welfare (PNDT Division)

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Nirman Bhawan, New Delhi Dated the 2thMay, 2015

To,

The Principal Secretarics (Health & FW), All States/UTs,

Subject:- Decisions taken in 22nd Meeting of the Central Supervisory Board (CSB) held on 13th October, 2014 under the Chairmanship of Hon'ble Minister of Health & FW - reg.

Sir,

I am directed to say that an Expert Committee was constituted to reexamine the provisions of the PC & PNDT Act, 1994 and rules framed thereunder. The expert committee had given clarifications regarding the powers of State Appropriate authorities and the closure of unused/idle/surrendered Ultrasound machines. The recommendations were placed in the 22nd Meeting of the Central Supervisory Board (CSB) [constituted under the Pre-conception and Pre-natal Diagnostics Techniques Act (PC & PNDT Act), 1994] held on 13th October, 2014 under the Chairmanship of Hon'ble HFM. The CSB has endorsed the following recommendations made by the Expert Committee:-

- (i) Same powers have been given to State Appropriate Authorities (SAA) as also to District Appropriate Authorities (DAA). SAA being an appellate authority over and above DAA with the jurisdiction for whole state, it has powers to direct the DAAs. In case DAA fails to implement the provisions of the PC & PNDT Act, 1994, SAA can take direct action against any violator of the PC & PNDT Act, 1994 and rules framed thereunder.
- (ii) The closure of unused/idle/surrendered Ultrasound machines lying in the registered clinics by the District Appropriate Authorities should be termed as <u>voluntary decommissioning of equipment</u> in place of sealing. Such terminology will de-legalize the process as it is voluntary in nature and is not done against any charge of offence.

2. In view of above recommendations of CSB, you are requested to take further action and disseminate the same among all stakeholders.

Yours faithfully,

Recommendation regarding setting up of an online grievance/complaint portal and a comprehensive website containing all relevant information regarding PCPNDT Act implementation [12 May 2015]

No. N.24026/06/2015 - PNDT Government of India Ministry of Health & Family Welfare (PNDT Division)

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Nirman Bhawan, New Delhi Dated the p^{*}May, 2015

To,

The Principal Secretaries (Health & FW), All States/UTs,

Subject:- Decisions taken in 22nd Meeting of the Central Supervisory Board (CSB) held on 13th October, 2014 under the Chairmanship of Hon'ble Minister of Health & FW - reg.

Sir,

I am directed to forward herewith the Minutes of the 22nd Meeting of the Central Supervisory Board [constituted under the Pre-conception and Pre-natal Diagnostics Techniques Act (PC & PNDT Act), 1994] held on 13th October, 2014 under the Chairmanship of Hon'ble HFM. The Central Supervisory Board constituted under the PC & PNDT Act, 1994 is apex policy making body for implementation of the Act.

2. The Central Supervisory Board (CSB), in aforesaid meeting has made following recommendations:-

- An Online grievance/complaint portal may be developed for receiving complaints against the unethical practice of sex selection.
- A comprehensive website containing all relevant information regarding implementation of the PC & PNDT Act, 1994.

3. In view of above recommendations of CSB, you are requested to take further necessary steps in this regard. In case if the State/UT already has such website/portal on the PC & PNDT Act, 1994, it is requested to ensure timely updation of all information.

Yours faithfully, Arg

Clarification regarding procedures to be followed in case of short term demonstration/ display of ultrasound/imaging machines in workshops/CME [14 May 2015]

No. V.11011/05/2013 - PNDT Government of India Ministry of Health & Family Welfare (PNDT Division)

> Nirman Bhawan, New Delhi Dated the المطلحة May, 2015

To.

The Principal Secretaries (Health & FW), All States/UTs,

Subject:- Clarification regarding procedures to be followed in case of short term demonstration/display of Ultrasound/Imaging Machines in the workshops/CME - reg.

Sir,

I am directed to say that an Expert Committee was constituted to re-examine the provisions of the PC & PNDT Act, 1994 and rules framed thereunder. The expert committee had given clarifications regarding the powers of State Appropriate authorities and the closure of unused/idle/surrendered Ultrasound machines. The recommendations were placed in the 22nd Meeting of the Central Supervisory Board (CSB) [constituted under the Pre-conception and Pre-natal Diagnostics Techniques Act [PC & PNDT Act], 1994] held on 13th October, 2014 under the Chairmanship of Hon'ble HFM. The CSB has endorsed the following recommendations made by the Expert Committee:-

" District Appropriate Authority may grant permission for education/training or display of diagnostic technologies as prescribed below.

- (i) For display at scientific exhibition, the organising body should take permission from the District Appropriate Authority for the display of diagnostic technologies/equipment specifying their details. DAA should ensure that these diagnostic technologies are not used for live demonstration and the organizing body has to take all responsibilities for the violations under the PC & PNDT Act, 1994, if any.
- For live demonstration at workshops and conferences, permission should be (iii) granted only when these diagnostic technologies are demonstrated in registered facilities under the PC & PNDT Act, 1994 with transmission facility for viewing by the delegates. Along with the request by the organizing body the of the diagnostic technologies/equipment used in the details workshops/conferences and list of experts/professional demonstrating technologies along with qualifications must be submitted. The registered facility that provides its premises for same should also intimate to their respective District Appropriate Authority with all information pertaining to the equipment used and experts/professional demonstrating technologies. In all live demonstration and conferences Appropriate Authority should ensure that all the record under the provision of the PC & PNDT Act are maintained and preserved. "

2. In view of above recommendations of CSB, you are requested to take further action and disseminate the same among all stakeholders.

Yours faithfully, ma

Section III: Good Practices

Annex A

Do's and Don'ts for Ultrasonography Centres/Genetic Counseling Centres

(Issued to all registered centres & facilities in Maharashtra – Government of Maharashtra good practice)

Do's

- 1. Get registered with concerned Appropriate Authority
- 2. Procedures to be carried out by qualified persons only
- 3. Procedures to be carried out only at place registered in Form B (Registration Certificate)
- 4. Record the reasons for doing sonography
- 5. Obtain written consent of pregnant women (for invasive tests) and preserve it
- 6. Get the registration renewed (in case nearing expiry). Apply 30 days before the date of expiry
- 7. Display the certificate of registration at place of business
- 8. Maintain records and preserve for two years or till the disposal of the court case whichever is later
 - a. B Form (registration Certificate 5 years till its validity)
 - b. D/E form (Genetic counseling centre/genetic laboratory)
 - c. F forms (completely filled)
 - d. G-Form consent (for invasive technique)
 - e. Laboratory results
 - f. Sonography plates/slides
 - g. Referral slips
 - h. Recommendations
- 9. Make records available for inspection to Appropriate Authority or the person authorised by Appropriate Authority
- 10. Inform the Appropriate Authority before purchase of new machines/s and get equipment registered with the Appropriate Authority
- 11. Maintain the register showing details of procedure (Sr.No.,Name of women, Address, name of spouse/father, Date of procedure)
- 12. Send complete report monthly by 5th day of next month to concerned Appropriate Authority

- 13. Display board in English and any other local language at place of centre/clinic "Disclosure of the sex of the foetus is prohibited under law"
- 14. Keep at least one latest copy of Act & Rules in centre/clinic
- 15. Fill up all details in F-form (all relevant points)
- 16. Surrender the certificate of registration in case of change of ownership, place or doctor performing the procedure
- 17. Apply for re-issuance of certificate of registration from the AA if there is change in management, owner or doctor conducting the procedure [Rule 13]
- 18. Display name and designation of person, including owner, employee or any other person associated with clinic, prominently on dress worn by him/her
- 19. Write name and designation of person doing procedure in full under his/her signature
- 20. Ensure that no provision of the Act & Rules are violated in any manner

Don'ts

- 1. Do not conduct sonography without referral slip which clearly states the purpose of sonography. (In case of self referral, mention it specifically)
- 2. Do not communicate the sex of foetus by words, signs or any other manner to any person, pregnant women or relatives
- 3. Do not purchase any new or old machines from anybody without intimating the Appropriate Authority
- 4. Do not transfer the certificate of registration
- 5. Do not employ or cause to be employed any person not possessing required qualification
- 6. Do not distribute any advertisement, in any form including internet regarding facilities of prenatal determination of sex or sex selection.

N.B.: This is not an exhaustive list but only most important aspects. The list of Do's and Don'ts is bound to be much longer if the whole Act and Rules are taken into account.

Annex B

Informer Scheme (Government of Maharashtra good practice)*

To, District Civil Surgeon District Hospital (All) Medical Officer Municipal Corporation, (All)

Subject: Regarding the Scheme of Award for the Informer under PCPNDT Act

Under the programme of the National Rural Health Mission, like last year, this year too, the person providing information on through sex determination tests being conducted at a Sonography centre, which is in violation of the PCPNDT Act shall be rewarded Rs. 25,000/-. Last year, 10 informers were rewarded Rs. 25,000/- each for the same. This year, no proposal has been made by you so far to the State Family Welfare office. It must be regretfully mentioned that you have not given enough publicity to this scheme that was in your field of operation.

You shall kindly give as much publicity as possible to this scheme in your field of operation and present proposals concerning the same before the State Family Welfare office. It shall kindly be noted that the person giving information on the violation of the PCPNDT Act shall be qualified for the reward only after a thorough investigation is carried out and the matter is reported in the court of law after having proven that the said Act has been violated and proposals should be made keeping this in view.

> State Appropriate Authority Commissioner (Family Welfare) and Director, National Rural Health Mission, Maharashtra, Mumbai

For Information and Further Action:

- 1) Director, Health Services, Mumbai
- 2) Additional Director, Health Services (F.W.) Pune

*Other state governments have also introduced similar schemes

Annex C

Regarding Permanent Inclusion of Agenda item 'Raising the Sex Ratio in the State' in the General body Meetings of Local Administrative Bodies (Government of Maharashtra good practice)

GOVERNMENT OF MAHARASHTRA

Public Health Department Government Circular No2011/No.273/F.W. Secretariat, Mumbai – 400 032 Date. 25.11.2011

Government Circular: According to the Census, 2011, the sex ratio has fallen to 883 girls for every 1000 boys from 913. If the number of girls keeps going on the downward spiral, there could be a steep increase in crimes against women and social inequalities. To counter this, efforts shall be made to put a stop to the sex determination tests at all levels possible. Considering the serious nature of this problem of the falling sex ratio, the elected representatives in the local administrative bodies need to be informed of the number of girls and boys born every month. Instructions regarding this are given below;

- A report consisting the total number of children born every month as well as the number of boys and girls shall be presented to the members of the District Planning Board, Municipalities, Zila Parishad, Panchayat Samiti, Gram Panchayats in the general body as well as monthly meetings. The responsibility for this lies with District Civil Surgeon, District Medical Officer, and Medical Officer of the Municipal Corporation who shall collect this information from all governmental/semi-governmental hospitals/ health centres.
- 2. Information regarding the total number of Sonography centres in the concerned area, investigations carried out by the Appropriate Authorities, legal action taken against the centres that are found to have violated the law shall be included in the above mentioned information.
- An appeal shall be made in the general body meeting to provide any information to the Appropriate Authorities on the Sonography centres that are found to be violating the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994 (Revised) 2003.
- 4. It shall be carefully noted that the discussions on this subject shall be included in the minutes of the meetings.

- 5. The Chief Executive Officer, Zila Parishad shall give instructions to the Panchayat Samitis and Gram Panchayats under his/her authority regarding the same.
- 6. The District Collectors shall immediately distribute these instructions to the officers of the municipalities for implementation.

The District Collector shall prepare a Press Release informing the total number of children born every month including the number of boys and girls through District Information Officer.

All District Collectors shall seek reports on whether the above mentioned instructions are followed and implemented in their respective districts every month and submit a report on the same to the Additional Director, Health Services, Family Welfare, Pune. The Additional Director, Health Services, Family Welfare, Pune shall submit a combined trimonthly report to the Government of Maharashtra.

For and as per the order of the Governor of Maharashtra,

(P. G. Deshmukh) Under Secretary, Government of Maharashtra

To,

Upper Chief Secretary (Revenue and Forest Department), Secretariat, Mumbai

Secretary (Urban Development Department) / (Rural Development Department), Secretariat, Mumbai

Commissioner (Family Welfare) and Director, National Rural Health Mission, Mumbai

Director, Health Services, Mumbai

Divisional Commissioner (All)

District Collectors (All)

Commissioner, Municipal Corporation (All)

Chief Executive Officer, (All)

District Civil Surgeon (All)

District Medical Officer (All)

Medical Officer, Municipal Corporation (All)

Additional Director, Health Services, Family Welfare, Pune (With request to bring to notice to all the concerned officers in the office)

Ministry of Health and Family Welfare Government of India www.mohfw.nic.in