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.

To

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 conditions; namely-

(a) The portable machines being used, within the premises it is registered for providing services to the indoor patients and
(b) As a part of a mobile medical unit offering a bouquet of other health and medical services;

(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**

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) 9/10/2014
Director (PNDT)
Tel: 011-23063628

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

F. No.12011/25/2014-PNDT
Government of India
Ministry of Health & Family Welfare
(PNDT Section)

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

To,

The Chairperson
State Appropriate Authority
All States/UTs

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

Sir/Madam,

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.

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.

7. Kindly acknowledge the receipt of this letter

Yours faithfully,

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

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