The Assisted Reproductive technology (Regulation) bill

Dr. Samit Sekhar,
M.B.B.S
Master of Men’s Health and Andrology (Australia)
Embryologist and Executive Director
Kiran infertility centre
Hyderabad & Gurgaon
Joint Secretary, INSTAR
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Government invited suggestions from the Stakeholders and Public in General and Comments regarding the same by Email.

**Architect** - Ministry of Health and Family welfare-Govt. Of India.
What is the aim of the ART Regulation bill?
**Aim** - proper regulation and supervision of ART clinics and banks in India and for prevention of misuse of this technology including Surrogacy and for safe and ethical practice of ART services.
How does the health ministry propose to regulate the ART Technology in India?
By establishing

- National Advisory Board
- the State Advisory Board
- the National Registry for the accreditation & Supervision for ART Clinics and banks.
Define Artificial Insemination?
Artificial Insemination

Definitions:

a) “Artificial insemination” means the procedure of artificially transferring semen into the reproductive system of a woman and includes insemination with the husband’s semen or with the donor’s semen.
What is Assisted Reproductive technology?
“Assisted reproductive technology”, with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive tract of a woman.
What are the Definitions of ART bank and ART Clinic?
a) “Assisted reproductive technology bank” means an organization that is set up to supply sperm or semen, oocytes or oocyte donors and surrogate mothers to the assisted reproductive technology clinics or their patients;

b) “Assisted reproductive technology clinic” means any premises, other than the clinics of AYUSH System of Medicine, equipped with the requisite facilities for carrying out the procedures related to the assisted reproductive technology;
What is the procedure for registration of ART bank or ART clinic?
PROCEDURES FOR REGISTRATIONS

No assisted reproductive technology clinic and assisted reproductive technology bank shall practice any aspect of assisted reproductive technology, or use any premises for such purposes, without registering as the assisted reproductive technology clinic or assisted reproductive technology bank with the Registration Authority.

The registration granted under this section shall be valid for a period of three years from the date of registration granted by the Registration Authority.
What are the Duties of an Assisted Reproductive Technology Clinic?
The assisted reproductive technology clinics shall provide professional counseling to commissioning couple about all the implications and chances of success of assisted reproductive technology procedures in the clinic in India and internationally, and shall also inform commissioning couple of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the commissioning couple arrive at a informed decision that would be most likely to be the best for the commissioning couple.
The assisted reproductive technology clinics and Assisted Reproductive Technology Banks shall ensure that information about clients, donors and surrogate is kept confidential and that information about assisted reproductive technology treatment shall not be disclosed to anyone other than a central database to be maintained by the National Registry for Assisted Reproductive Technology Clinics and Banks in India of the Indian Council of Medical Research except in a medical emergency at the request of the person or persons or the closest available relative of such person or persons to whom the information relates, or by an order of a court of competent jurisdiction.
No assisted reproductive technology clinic shall consider conception by surrogacy for patients for whom it shall normally be possible to carry a baby to term:

No assisted reproductive technology clinic shall obtain or use sperm or oocyte donated by a relative or known friend of either of the parties seeking assisted reproductive technology treatment or procedures.
No assisted reproductive technology procedure shall be performed on a woman below the age of twenty three years and above the age of fifty years and the concern Gynecologist shall furnish certificate indicating that the woman is medically fit to opt for the ART services.

No assisted reproductive technology procedure shall be performed on a man below the age of twenty three years and above the age of fifty five years.

No assisted reproductive technology clinics and assisted reproductive technology banks shall freeze any human embryos and/or gametes without specific instructions and consent in writing from all the parties seeking assisted reproductive technology in respect of what should be done with the gametes or embryos in case of death or incapacity of any of the parties.

No assisted reproductive technology clinic shall use any human reproductive material to create a human embryo or use an in vitro human embryo for any purpose without the specific consent in writing of all the parties to whom the assisted reproductive technology relates.

The consent of any of the parties obtained under this section may be withdrawn at any time before the human embryos or the gametes are transferred to the concerned woman’s uterus.
All consent forms and agreements signed by all the parties seeking ART services including surrogacy shall be in local language also so that all the parties including surrogate mother and the gamete donor can understand the contents of the consent forms and agreements.

In the event of the closure of any assisted reproductive technology clinic and assisted reproductive technology bank before the expiry of the period of ten years under sub-section the assisted reproductive technology clinic and assisted reproductive technology bank shall immediately transfer the records to a central database of the National Registry of Assisted Reproductive Technology Clinics and Banks in India to be set up under Indian Council of Medical Research, New Delhi.
What are the guidelines in relation to Gamete Donation?
• Oocyte donor shall be an ever married woman having at least one live child of her own with minimum age of three years and shall be allowed to donate oocytes only once in her life and not more than seven oocytes shall be retrieved from the oocyte donor.
• The eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient.
• One sample of semen supplied by an assisted reproductive technology bank shall be used by the assisted reproductive technology clinic only once on only one recipient.
• No woman should be treated with embryos derived from the gametes of more than one man or woman during one treatment cycle.
• An assisted reproductive technology clinic shall never mix semen from two individuals before use.
What is the age limit of ART for both men & women?

No assisted reproductive technology procedure shall be performed on a woman below the age of twenty three years and above the age of fifty years and the concern Gynaecologist shall furnish certificate indicating that the woman is medically fit to opt for the ART services.

No assisted reproductive technology procedure shall be performed on a man below the age of twenty three years and above the age of fifty five years.
What is the age limit for both egg and sperm donor?

Oocyte donor shall be an ever married woman having at least one live child of her own with minimum age of three years and shall be allowed to donate oocytes. In the event that the man intending to act as sperm donor is married, the consent of his spouse shall be required before he may act as sperm donor.
Marital status of egg and sperm donor and spousal content?

Oocyte donor shall be an ever married woman having at least one live child of her own with minimum age of three years. Man intending to act as sperm donor is married, the consent of his spouse shall be required before he may act as sperm donor.
How many eggs can be retrieved from egg donor?

Once in her life and not more than seven oocytes shall be retrieved from the oocyte donor
How many eggs can be shared from one egg donor?

The eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient.
What will be the law and implications in case of death of an egg donor?

In case of death or disability of the oocyte donor, it shall be presumed to have been caused by the negligence of the assisted reproductive technology clinic unless proven otherwise.
What Is the duration of maintenance of medical records?
All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules made under shall be preserved for a period of ten years and after which the records shall be transferred to the National Registry.
what are the presumed negligence's on behalf of an ART clinic
• The applicant makes wilful default in doing anything required of him by or under this Act or the rules or the regulations made there under;
• The applicant violates any of the terms or conditions of the approval given by the Authority:
• The applicant is involved in any kind of unfair practice or irregularities.
• falsely represents that the services are of a particular standard grade represents that the holder of registration has approval or affiliation which such applicant does not have;
• makes a false or misleading representation concerning the services;
• the holder of registration permits the publication of any advertisement relating to infertility or surrogacy whether in any newspaper or otherwise of services that are not intended to be offered.
What is the punishment in case of alleged negligence?
Any medical geneticist, gynecologist, registered Offences and medical practitioner or any person who owns or operates any assisted reproductive technology clinic or Assisted reproductive technology bank is employed in such a assisted reproductive technology clinic or assisted reproductive technology bank and renders his professional or technical services to or at such assisted reproductive technology clinic or assisted reproductive technology bank, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made there under shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to rupees ten lakhs or with both and on any subsequent contravention, with imprisonment for a term which may extend to seven years or with fine which may extend to rupees fifteen lakhs or with both.

Whoever contravenes any of the provisions of this Act or Punishment any rules made there under, for which no penalty has been for contravention elsewhere provided in this Act, shall be punishable with of provisions imprisonment for a term which may extend to five years of Act or with fine which may extend to rupees ten lakhs or with rules for both and in the case of continuing contravention with an which no additional fine which may extend to rupees fifty thousand specific.
Who is the appellate authority?
what is your general view on the current bill?
Thank You