

The Assisted Reproductive Technology (Regulation) Bill, 2020

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Manifest pedagogy:

India has become the hub of the global fertility industry and medical tourism. This has resulted in multitude of legal, ethical and social issues and there are no standardizing protocols available. In order to regulate India's fertility treatment industry, the Assisted Reproductive Technology (Regulation) Bill, 2020, will be considered for passing in the Lok Sabha this winter session.

In news: Winter Session: Bill on assisted reproductive technology tabled in Lok Sabha

Placing it in syllabus: Law & Policy

Static dimensions:

- What is Assisted reproductive technology (ART)?
- Historical background
- Difference between Surrogacy and ART

Current dimensions:

- The need for ART regulation in India
- Provisions of the bill

Content:

What is Assisted reproductive technology (ART)?

- Assisted Reproductive Technology refers to a range of medical interventions that help in fertility and reproduction

These include procedures such as:

- gamete donation (the use of donor sperm or eggs),
- intrauterine insemination (a procedure in which sperm is artificially inserted into the uterus),
- in-vitro fertilisation (the egg is fertilised by sperm outside the body and then transferred to the uterus),
- intra cytoplasmic sperm injection (a form of IVF in which a live sperm is injected into the centre of an egg),
- preimplantation genetic diagnostics (the screening of an embryo for genetic conditions prior to implantation/pregnancy)
- gestational surrogacy (in which a surrogate carries the baby in her uterus but has no genetic link to it), and

Historical background:

- The world's first test tube baby, Louise Brown was born on 25th July 1978.
- About two months later, the world's second and India's first IVF baby, Kanupriya alias Durga was born in Kolkata.
- Since then the field of Assisted Reproductive Technology (ART) has grown exponentially.
- The ICMR drafted the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India in 2005 as the first ever national guidelines for laying down standards of conduct for surrogacy in India.
- The Law Commission of India suo motu took up the subject of the need for legislation to regulate Assisted Reproductive Technology Clinics as well as rights and obligations of parties to a surrogacy.
- The Law Commission presented its 228th Report in 2009 which stated that an active legislative intervention is required to facilitate correct uses of the new technology, i.e. ART and legalization of surrogacy.

- In 2020, the ART bill was introduced in the monsoon session of Parliament but the proceedings were curtailed due to Covid, leading to further delay.

Why has ART become so popular?

- ***Social norms:*** Infertility is seen as a major problem as kinship and family ties are dependent on progeny.
- ***Social stigma of being childless:*** A woman is respected as a wife only if she is mother of a child, so that her husband's masculinity and sexual potency is proved and the lineage continues
- ***Lengthy adoption processes:*** Any person who is Indian, Non-Indian or a foreigner is eligible to adopt a child as per Indian law. Indian culture doesn't enable "open adoption". Since India takes after "shut adoption", arrangement about the birth parent/s isn't revealed. But it takes a long time to be verified and matched to a baby.
- ***Ease of access to ART clinics:*** ART clinics are easily accessible. According to a registry maintained by the Indian Council of Medical Research, there are 1,269 ART clinics in India (as on November, 2019).

Difference between Surrogacy and ART:

Surrogacy:

- Surrogacy is an infertility treatment where a third person (woman) is involved who is the surrogate mother
- Surrogacy is allowed for only Indian Married Couple
- Commercial surrogacy is not allowed in India

ART:

- Assisted Reproductive technology treatments can be availed by the commissioning couple themselves and no third person is involved

- ART procedures are open to married, live in partners, Single Woman and also foreigners
- No Commercial donors allowed

The need for ART regulation in India:

Assisted Reproductive Technology (ART), including In Vitro Fertilization (IVF), has given hope to many persons suffering from infertility but introduced a plethora of legal, ethical and social issues.

- **Commercialisation of ART Clinics without approvals:** As of today, anyone can open an infertility or assisted reproductive technology (ART) clinic; no permission is required to do so. There has been, consequently, a mushrooming of such clinics around the country
- **Medical Tourism:** India's fertility industry is an integral part of the country's growing medical tourism industry, which experienced 30% growth in 2000 and 15% growth between 2005 and 2010. Despite so much activity in India, there is no standardisation of protocols yet and reporting is still very inadequate. Furthermore, there are only guidelines of ART, and no law still exists.
- **Non-uniformity of costs and standards:** There are no standard operating procedures to ensure "uniform costs" and "global quality standards" across India.
- **Moral issues:** criticism that surrogacy leads to commoditization of the child, breaks the bond between the mother and the child, interferes with nature and leads to exploitation of poor women in underdeveloped countries who sell their bodies for money.
- **Sex selective treatment:** The technology can be misused to get sex selective offspring which may have disastrous demographic and social implications.
- **Preventing exploitation of women and children:** The need to regulate the Assisted Reproductive Technology Services is mainly to protect the affected Women and the

Children from exploitation. The oocyte donor needs to be supported by an insurance cover, protected from multiple embryo implantation and children born through Assisted reproductive technology should be provided all rights equivalent to a Biological Children.

- Consequently, infertile couples will be more ensured/confident of the ethical practices in ARTs.

Objectives of the bill:

The objectives of the the Assisted Reproductive Technology Regulation Bill 2020 as laid down in the standing committee report are:

- To regulate ART services and protect the women and children involved from exploitation.
- To provide insurance cover for egg donors and protection from multiple embryo implantation (due to the health risks involved for mother and child).
- To provide rights to children born through ART equivalent to rights provided to biological children.
- To regulate cryopreservation [cold storage] of sperm, eggs, and embryos by ART banks.
- To make pre-implantation genetic testing mandatory for the benefit of a child born through assisted reproductive technology.
- To ensure proper registration of ART clinics and banks.

Provisions of the bill:

Definition of Assisted Reproductive Technology (ART):

- The Bill defines ART to include all techniques that seek to obtain a pregnancy by handling the sperm or the oocyte (immature egg cell) outside the human body and transferring the gamete or the embryo into the reproductive system of a woman.

- Examples of ART services include gamete (sperm or oocyte) donation, in-vitro-fertilisation (fertilising an egg in the lab), and gestational surrogacy (the child is not biologically related to surrogate mother).
- ART services will be provided through: (i) ART clinics, which offer ART related treatments and procedures, and (ii) ART banks, which store and supply gametes.

Regulation of ART clinics and banks:

- The Bill provides that every ART clinic and bank must be registered under the National Registry of Banks and Clinics of India.
- The National Registry will be established under the Bill and will act as a central database with details of all ART clinics and banks in the country.
- State governments will appoint registration authorities for facilitating the registration process. Clinics and banks will be registered only if they adhere to certain standards (specialised manpower, physical infrastructure, and diagnostic facilities).
- The registration will be valid for five years and can be renewed for a further five years.
- Registration may be cancelled or suspended if the entity contravenes the provisions of the Bill.

Conditions for gamete donation and supply:

- Screening of gamete donors, collection and storage of semen, and provision of oocyte donor can only be done by a registered ART bank.
- A bank can obtain semen from males between 21 and 55 years of age, and oocytes from females between 23 and 35 years of age.
- An oocyte donor should be an ever-married woman having at least one alive child of her own (minimum three years of age).
- The woman can donate oocyte only once in her life and

not more than seven oocytes can be retrieved from her.

- A bank cannot supply gamete of a single donor to more than one commissioning couple (couple seeking services).

Conditions for offering ART services:

- ART procedures can only be carried out with the written informed consent of both the party seeking ART services as well as the donor.
- The party seeking ART services will be required to provide insurance coverage in the favour of the oocyte donor (for any loss, damage, or death of the donor).
- A clinic is prohibited from offering to provide a child of pre-determined sex.
- The Bill also requires checking for genetic diseases before the embryo implantation.

Rights of a child born through ART:

- A child born through ART will be deemed to be a biological child of the commissioning couple and will be entitled to the rights and privileges available to a natural child of the commissioning couple.
- A donor will not have any parental rights over the child.

National and State Boards:

- The Bill provides that the National and State Boards for Surrogacy constituted under the Surrogacy (Regulation) Bill, 2019 will act as the National and State Board respectively for the regulation of ART services.
- Key powers and functions of the National Board include:
 - (i) advising the central government on ART related policy matters,
 - (ii) reviewing and monitoring the implementation of the Bill,
 - (iii) formulating code of conduct and standards for ART clinics and banks, and

- (iv) overseeing various bodies to be constituted under the Bill.
- The State Boards will coordinate enforcement of the policies and guidelines for ART as per the recommendations, policies, and regulations of the National Board.

Offences and penalties:

Offences under the Bill include:

- (i) abandoning, or exploiting children born through ART,
- (ii) selling, purchasing, trading, or importing human embryos or gametes,
- (iii) using intermediates to obtain donors,
- (iv) exploiting commissioning couple, woman, or the gamete donor in any form, and (
- v) transferring the human embryo into a male or an animal.

The quantum of punishment has also been specified:

- These offences will be punishable with a fine between five and ten lakh rupees for the first contravention.
- For subsequent contraventions, these offences will be punishable with imprisonment for a term between eight and 12 years, and a fine between 10 and 20 lakh rupees.
- Any clinic or bank advertising or offering sex-selective ART will be punishable with imprisonment between five and ten years, or fine between Rs 10 lakh and Rs 25 lakh, or both.
- No court will take cognisance of offences under the Bill, except on a complaint made by the National or State Board or any officer authorised by the Boards.