

**PARLIAMENTARY COMMITTEE ON SOCIAL JUSTICE AND
EMPOWERMENT**

The Assisted Reproductive Technology (Regulation) Bill, 2020 (Art)

ONE HUNDRED AND TWENTY-NINTH REPORT

CHAPTER 1 INTRODUCTION

The Assisted Reproductive Technology Bill (Regulation) Bill, 2020 provides for the **regulation and supervision for the Assisted Reproductive Technology clinics and banks, prevention of misuse, safe and ethical practice of assisted reproductive technology services**. India has registered the highest number of ART facilities, and every year a number of cycles are performed as Assisted Reproductive Technology and In Vitro Fertilization. The international Legislative march towards regulating the ART services makes it incumbent upon the Government of India to proceed ahead with the progressive legislation as proposed in the Bill.

This bill intends to protect women and children from exploitation and provide rights to children born through assisted reproductive technology equivalent to rights of biological children. The bill intends to support the oocyte donors through an insurance cover from multiple embryo implantations..

The ART bill is expected to have an impact on the registration of all clinics, control unethical ART practices, improve the quality of ART services, give couples the assurance that ART is conducted in an ethical manner.

ORIGIN OF THE BILL

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 presented its 228th Report in 2009 which stated the need for active legislation to facilitate the correct use of the technology.

SALIENT FEATURES

- The bill sets a **provision for National and State Boards** to advise, review, and monitor the bill's implementation and formulate a Code of Conduct and standards for ART clinics.
- The ART focuses on registration and **regulation of the ART clinics in the National Registry** that is to be established. To create a database and to create a standard to manage an ART clinic.
- By setting up **eligibility criteria for donors & commissioning parties**, conditions for offering such services, and also the bill briefly mentioned the insurance coverage for the donor from a commissioned couple.
- The ART bill elaborately talks about the duties and **responsibilities of the clinics** and banks like procedures and record keeping. And also talks about the penalties for those who don't follow the rules that have been set.
- The **rights of the children born through ART**, deemed to be biological children and entitled to the rights & privileges available to a natural child.

CHAPTER 2 VIEWS OF THE DEPARTMENT OF HEALTH RESEARCH

Deliberations with officials of Health Departments involved discussions of the objectives, the likely impact and the challenges faced in implementations of various provisions of the Bill. During the course of presentation by the ICMR, according to trend analysis **the industry would be a 6 billion USD industry by the year 2030.**

The ART services include the following services :

- Ovarian stimulation
- Egg Retrieval
- Invitro fertilisation - IVF
- Intra- Uterine Insemination - IUI
- Intracytoplasmic sperm injection - ICSI
- Embryo transfer

- Gamete Intrafallopian Transfer - GIFT
- Zygote Intra fallopian transfer- ZIFT
- Microsurgical epididymal sperm aspiration- MESA
- Testicular sperm extraction- TESE

The Bill was drafted with the objectives of **registration of ART clinics and banks, specify age of the couple or woman who can avail ART, provide insurance coverage for donors, specify the number of embryos to be planted, disallow sex selection at every stage of embryo fertilisation, allow pre-implantation genetic testing and screen the embryo for preventing births with genetic disorders, ensure appropriate storage of embryos and gametes, have penal provisions for unethical practices in clinics etc**

The deliberations discussed the possibility of ART procedures being exploited through negligence in performing surgical procedures of harvesting eggs and unethical preservation of ovum and sperm in ART banks amongst others and due to a plethora of ethical, legal and social issues, the 228th Law Commission Report recommended bringing an active legislative intervention to facilitate the correct use of ART. The Departmental-Related Standing Committee of Health and Family Welfare while examining the Surrogacy Regulation Bill, 2016, had also recommended bringing a regulation for the Assisted Reproductive Technology Clinic and Banks along with the Surrogacy Regulation Bill.

Beneficiaries of the Assisted Reproductive Technology (ART) Bill :

- Indian Married Couple, (Man and Woman)
- Indian Single Woman
- Foreigners as a couple (man and woman) or a single woman

The Bill specified the age of the commissioning couple to be between 19 to 50 years in case of females and between 22 to 55 years in case of males on the day of application for such treatment and to be married for 1 year.

Single women i.e. divorced, widowed and unmarried have been permitted to avail ART services. The Bill allows the single unmarried woman to avail ART services keeping in view that adoption is allowed for single women.

Abortion and Reproductive Autonomy – The Puttaswamy case and Suchita Srivastava v Chandigarh Administration, both clearly mentioned that reproductive rights included a woman's entitlement to carry a pregnancy to its full term, to give birth, and to subsequently, raise children; and that these rights form part of a woman's right to privacy, dignity, and bodily integrity. These judgments hold an important bearing on the sexual and reproductive rights of women.

About Oocyte donor and sperm donor - An oocyte donor shall be married, at least with a child of her own at a minimum of 3 years old. She can donate only once in her life and not more than 7 oocytes shall be retrieved from the oocyte donor. Written consent is must as per ART bill and insurance coverage will be provided as such amount and for such period as may be prescribed in favour of the oocyte donor by the commissioning couple or woman from an insurance company or an agent recognized by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999.

Composition of National Board and State Board

National Board	State Board
Chairperson (Ex officio) - Minister in-charge of the Ministry of Health and Family Welfare	Chairperson (ex officio) - Minister in-charge of Health and Family Welfare in the State
Vice chairperson (Ex officio) - Secretary to the GoI in-charge of the Department dealing with the surrogacy matter	Vice chairperson (Ex officio) - Secretary in-charge of the Department of Health and Family Welfare

<p>Member, ex officio - three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States</p>	<p>Member, ex officio - three women members of the State Legislative Assembly or Union territory Legislative Council</p>
<p>Member, ex officio - Director General of Health Services of the Central Government</p>	<p>Member, ex officio - Director General of Health and Family Welfare of the State Government</p>
<p>Ten expert members to be appointed by the Central Government</p>	<p>Ten expert members to be appointed by the State Government</p>
<p>Member, ex officio - three Members of the Ministries of Central Government in charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary</p>	<p>Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees</p>

FUNCTIONS OF THE BOARDS

- **Review, Monitor and advise** the central government on policy as well as implementation of the ART
- **Lay down Code of Conduct** to be followed by ART clinics and banks and to set a minimum standard for physical infrastructure of ART clinics.
- Act as **appellate authority** for national and state bodies and Oversee performance of various bodies constituted under the act.
- Ensuring **update of national registry** and passing orders as per the provision under the act.

Composition of the National and State Authority – It comprises officers from the health and family welfare department, officers from the law department of the state/UT, an eminent woman representative from a woman's organisation.

Registration of ART clinics – Every clinic/bank conducting assisted reproductive technology, partly or exclusively shall, register under sub-section (1) to the state registration authority, under 60 days from the day of notification. Registration is provided within a period of a month and the registration valid for 5 years. If the application is rejected, the clinics/banks appeal against rejection of registration.

Penalties - Abandoning or exploiting the child/children, selling embryo/gamete, exploiting commissioning woman and couple will be facing imprisonment for not less than 8 - 12 years and will be fined 10 -12 lakhs.

As mentioned during the process sex selection of the baby is punishable for a term of 5 – 10 years of imprisonment and they will be fined 10 – 25 lakhs or both.

Safeguards of the bill

- Child born through ART shall be deemed a biological child of the commissioned couple.
- The child shall be entitled to all the rights and privileges as a biological child.
- Insurance coverage for the oocyte donor
- Professional counselling by the state board for commissioning couple and donor woman
- No sex selection and no foetal reduction as the number of embryos to be Implanted will be meticulously governed.
- Provision for proper storage of embryos and gametes.

Complaint and Redressal Mechanism - The clinic or bank or the commissioning couple or the woman may, within a period of thirty days from the date of rejection of application, suspension or cancellation of registration passed by the Registration Authority as per section 19, prefer an appeal against such order to

- The State Government, where the appeal is against the order of the Registration Authority of a State.
- The Central Government, where the appeal is against the order of the Registration Authority of a Union territory, in such manner as may be prescribed in rules.

CHAPTER 3- VIEWS OF STAKEHOLDER/EXPERTS

Through deliberations with representatives of various Associations in the field of Assisted Reproductive Technology, The Committee received stakeholder opinion from organizations/experts/NGOs/Ministries and others on the Assisted Reproductive Technology (ART) 2020.

The majority of them noted that the following points should be addressed.

- There should be a **national body to monitor the ART Act**, in the common memorandum the chairman of the committee stated that there should be a centralised body that consist of (a) an Eminent Reproductive Specialist with at least 15 years of experience (b) 2 Gynaecologists with at least 15 years of experience (c) A legal practitioner with at least 15 years of experience. (d) An Embryologist (e) A Social Scientist.
- Another common pointer was that the act left out the **LGBTQ community, single men and live-in-couples** and recommended to be more inclusive for them.
- Majority suggested the inclusion of infertility under the Ayushman Bharat Scheme
- **Need of Uniform Software** for the National Registry for better management and integration.
- The expressions -"Natural and legal child" should be used in the Bill instead of biological child as it would be legally sound.
- **Proper Insurance and compensation mechanism** should be established to the donor and the child.

During subsequent meetings, clause by clause examination of the Bill was conducted, during these readings the committee laid out suggestions that included changes in certain provisions of the Bill and accordingly the clauses were adopted or rejected.

RECOMMENDATIONS OF THE COMMITTEE

- The **screening and storage of semen** and oocyte donors should be done by a registered bank as an independent entity under the provision of this Act.
- **Commercialization of gamete donation must be prohibited** in letter and spirit by effective implementation of the provisions of the proposed legislation and ensuring that ART services does not spill over as a money making business.
- As the National Surrogacy Board will also regulate the ART service, it is recommended that the name of the board should be named as “**National ART and Surrogacy Board**” and same for the state boards.
- While appointing ten expert members of the national board the central government should assure that eminent **reproductive specialist**.
- The National board consists of eminent experts in the field, women welfare representatives, representatives from civil society working on women’s health and child issues to **ensure monitoring of the implementation** that includes redressal of complaints and negligence.
- To avoid duplication of institutional arrangement and to implement for ART act and Surrogacy (Regulation) Act a common institution should be functioning and may be named as “**Appropriate ART and Surrogacy Registration Authority (AASRA)**”
- The committee also recommended that an **independent and impartial grievance redressal cell** should be established to deal with complaints against ART Clinic/bank to the Registration Authority.
- People with medical conditions be allowed to access the facility of ART services.
- The committee recommended that the **Personal Data Protection (PDP) Bill 2019 be included** in this bill to make sure that data is anonymized at the primary source to minimize its leakage while in transit.

- The bill should have informed consent from all the persons concerned with ART services to make sure the stakeholders can make informed and voluntary choices to accept or decline the procedure.
- A provision should be included to **safeguard the data** before it is made available for any research and so the same provision should mention about punishment in case of any data breaches.
- There should be a provision of **Uniform Software for the National Registry** to ensure better integration, data management, and privacy protection of donors and the commissioning couple
- There needs to be a balanced approach regarding retrieving a reasonable number of oocytes based on medical conditions of the donor and restricting it to retrieval of seven oocytes.
- Government enhanced **ART facilities in medical colleges** or district hospitals by opening infertility clinics for the availability of ART facilities to the mass.
- While formulating rules, it is also desired that the Department of Health Research consider making **prerequisite conditions of price registration** as the same would give a sigh of relief to poor parents willing to have a child at a reasonable cost.
- It was recommended to draw a plan for a **specialisation ART course of one or two years in the IVF field** and only then the person be allowed to operate the IVF center.
- To avoid the possibility of exploitation of the deprived, there was a need for **regularization of the protocol of IVF centres.**
- There should be an andrologist/urologist in the ART clinics to ascertain the best candidate for sperm retrieval, also to assist in optimising ART outcome and, to tackle potentially treatable underlying conditions.