

Standing Committee Report Summary

The Assisted Reproductive Technology (Regulation) Bill, 2020

- The Standing Committee on Health and Family Welfare (Chair: Mr. Ram Gopal Yadav) submitted its report on the Assisted Reproductive Technology (Regulation) Bill, 2020. The Bill seeks to regulate assisted reproductive technology (ART) services in India. ART is defined 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 (sperm or egg) into the reproductive system of a woman.
- **ART banks:** Under the Bill, an ART bank acts as a registered entity for: (i) screening of gamete donors, and (ii) collection, screening, and storage of semen. The Committee observed that the role of the ART bank is not clear in the definition. Further, screening of gamete donors is a complicated process, which needs the presence of specialised doctors. ART banks may not have such doctors. The Committee recommended that the Department of Health Research should clearly define the role of ART banks, and the specialists required in them. Further, screening of gametes should be done by an ART clinic and the banks should be responsible for the collection, storage, and supply of gametes.
- **Bodies regulating ART and surrogacy:** The Committee noted that the Appropriate Authority under the Surrogacy (Regulation) Bill, 2020 and the Registration Authority under the ART (Regulation) Bill, 2020 are similar in composition and certain functions. These functions include: (i) grant, suspension, or cancellation of registration of a clinic or bank, (ii) enforcing standards of operation for clinics and banks, and (iii) investigating complaints of violation of the Act and related rules. The Committee recommended that the central government should constitute a common institution called Appropriate ART and Surrogacy Registration Authority to discharge these similar functions under both the laws. Further, since the National Surrogacy Board will also regulate the ART services, the Committee recommended that it should be renamed as the National Surrogacy and ART Board.
- **Grievance redressal:** As per the Bill, every ART clinic and bank will have a grievance redressal cell. The Committee recommended that a 30-day timeframe should be provided for addressing the concerns of patients. In addition, an individual may approach Courts with complaints regarding ART services. However, to avoid burdening the courts, the Bill must provide for setting up an independent and impartial grievance redressal cell in the Registration Authority. This would address complaints against ART clinics and banks.
- **Data protection and privacy:** The Bill specifies that the data collected by ART clinics and banks (such as procedures being undertaken) must be transferred to a central database (National Registry) within a month of receiving the data. The ART clinics and banks must store this data for at least ten years. The National Registry must share this data with the National Board for the purpose of inspection. The Committee noted that these are personal data which may lead to the identification of the commissioning couples, women, or donors. The Committee recommended that the personal data of patients and commissioning couples should be converted to a form in which a data principal (individual to whom the data belongs) cannot be identified. The data should be collected for a specific purpose and kept for the period required for that purpose. Further, the Bill should include provisions for anonymising the data at the primary source. Further, the Committee recommended that the confidentiality of the data should conform to the law as laid down in the judgment of Justice K.S Puttaswamy (Retd.) versus Union of India, the Personal Data Protection Bill, 2019 and the National Digital Health Blueprint issued by the Ministry of Health and Family Welfare.
- **Posthumous reproduction:** Posthumous reproduction refers to reproduction by using the gamete of a deceased person. The Committee suggested that posthumous reproduction should be permitted, even in the absence of prior consent of the deceased unless the deceased has previously objected to this.
- **Standardisation:** The Committee noted that the cost of ART services varies across clinics. It recommended that standard operating procedures should be formulated to ensure the uniform cost of ART services and global quality standards. Further, a monitoring mechanism should be set up under the National Board to prohibit commercialisation of the ART services by private service providers.

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