Issues for Consideration:
Assisted Reproductive Technology (Regulation) Bill, 2021

Background to the Bill

Assisted reproductive technologies (ART) refer to a range of fertility treatments aimed at aiding reproduction for couples suffering from infertility or to persons who may wish to have a child through artificial methods. These arrangements include in-vitro fertilisation (fertilising an egg in the lab), gamete donation (sperm or egg), and gestational surrogacy (where the child is not biologically related to the surrogate mother). As per private estimates shared with the Standing Committee on Health and Family Welfare (2017), around 2.8 crore couples in the reproductive age group in India are infertile and about 1% of these seek infertility evaluation.[1] Of the people seeking remedy for infertility, 20-25% undergo in vitro fertilisation treatment and of that, 1% may require surrogacy.

In 2005, the Indian Council of Medical Research (ICMR) issued guidelines to regulate clinics providing ART procedures (including surrogacy procedures).[2] The guidelines provide for registration of clinics offering ART services, permit single women and couples to access ART services, and allow ART banks to compensate donors. These guidelines also specify conditions for when surrogacy may be opted, and the compensation for surrogates.

In July 2019, the government introduced the Surrogacy (Regulation) Bill.[3] The Bill provides for the registration of surrogacy clinics, defines the eligibility criteria of commissioning couples and surrogates, and provides for the establishment of boards to advise the government on surrogacy policies. The Bill was passed by Lok Sabha in August 2019. In Rajya Sabha, the Bill was referred to a Select Committee of the House.[4] While examining the Bill, the Committee recommended introducing a comprehensive legislation to first regulate clinics and banks providing various fertility services, i.e., ART and surrogacy services.

The Assisted Reproductive Technology (Regulation) Bill, 2020 was introduced in Lok Sabha in September 2021 and was referred to the Standing Committee on Health and Family Welfare in October 2020. On December 1, 2021, Lok Sabha passed the ART Bill, with certain amendments.[5] In this note, we discuss the key provisions of the ART Bill, 2021 (as passed by Lok Sabha), and the key issues which still remain to be considered.

Key Features of the Bill

- **Provision of ART services**: 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. These include gamete donation (of sperm or egg), in vitro fertilization, and gestational surrogacy. ART services will be provided through: (i) ART clinics, which offer ART related treatments and procedures, and (ii) ART banks, which collect, screen and store gametes.
- **Registration of ART clinics and banks**: Every ART clinic and bank must be registered under the National Assisted Reproductive Technology and Surrogacy Registry. A National Registry will be established under the Bill, which will act as a central database with details of all ART clinics and banks in the country. Clinics and banks will be registered only if they adhere to certain standards (such as specialised manpower, physical infrastructure, and diagnostic facilities). The registration will be valid for five years and may be renewed. The central and state governments will appoint appropriate authorities to support registration related services such as maintenance of details of registration of assisted reproductive technology clinics and banks, cancellation and renewal of registration.
- **Boards:** The Bill provides that the National and State Boards constituted under the Surrogacy (Regulation) Bill, 2019 will also act as the National and State Boards for the regulation of ART services. Key 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 a code of conduct and standards for ART clinics and banks, and (iv) overseeing bodies constituted under the Bill. The State Boards will coordinate enforcement of policies and guidelines for ART as per the directions of the National Board.

Aditya Kumar
aditya@prsindia.org

December 4, 2021

- **Eligibility criteria for commissioning parties:** ART services may be commissioned by married couples or women where: (i) the woman is between 21 and 50 years of age, and (ii) the man is between 21 and 55 years. Married couples must also be infertile, i.e. unable to conceive after one year of unprotected coitus or suffer from any other proven medical condition which prevents conception.
- **Eligibility criteria for donors** A bank may obtain semen from males between 21 and 55 years of age, and eggs from females between 23 and 35 years of age. The woman may donate eggs only once in her life and not more than seven eggs may be retrieved from her. A bank must not supply gamete of a single donor to more than one commissioning party (i.e. couples or single women seeking services).
- **Conditions for offering services**: ART procedures must be conducted only with the written consent of the commissioning parties and the donor. The commissioning party will be required to provide insurance coverage in favour of the egg donor (for any loss, damage, or death). Clinics are required to check for genetic diseases before implantation and are prohibited from providing any sex-selective services (e.g. sex determination).
- **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.
- **Duties of ART Clinics and Banks**: ART clinics and bank must share information related to: (i) enrolment of the commissioning parties and donors, (ii) procedures being undertaken, and (iii) outcome of the procedure, with the National Registry. Further, they must maintain records of all donations for at least 10 years, after which the records must be transferred to the National Registry. While using human gametes and embryos, ART clinics and banks must: (i) harvest eggs in the manner specified by regulations, and (ii) place such number of eggs or embryos in the uterus of the woman as may be specified by regulations.
- **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, and (iii) exploiting the commissioning couple, woman, or the gamete donor in any form. 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 between three and eight years, and a fine between 10 and 20 lakh rupees. A court will take cognisance of an offence only on a complaint by the National or State Board.

Highlights of the Lok Sabha debate on the Bill

Key discussions on the Bill during the debate on the Bill in Lok Sabha include:[6,7,8,9]

- **Inclusion of single parent and LGBTQ community:** During the discussion, Members highlighted that the Bill allows only married couples and single women to avail ART services. This excludes single men and the LGBTQ community from benefits of ART services. Members argued that this may violate the right to equality under Article 14 of the Constitution. In response to this, the Minister of Health and Family Welfare clarified that single women (includes the LGBTQ community) will have access to ART services and other benefits specified as per the Bill. However, single men will not be able to avail such services as they are not allowed to adopt a child as per the current adoption rules.[10]
- **Qualification of Members in appropriate authority:** The Bill provides that the national and state level appropriate authorities (which will grant registration to clinics and banks, and enforce standards to be fulfilled by them) must have a registered medical practitioner as a member. Members argued that any medical practitioner may not have expertise related to ART services. Therefore, experts such as obstetricians and gynaecologists must be included as members in these authorities. In response to this, the Health Minister stated that the National and State Boards will have 10 expert members (such as gynaecologist and embryologist).
- **IVF facility at ART banks:** It was highlighted that eggs are produced in labs, which are then stored in ART banks. Thus, the facilities of IVF lab must be made available at ART banks. The Health Minister agreed on this and stated that such enabling provisions will be included in the rules to be notified at a later stage.

Issues to consider

Overlap in the regulation of surrogacy services and other ART services

In 2016, a Bill was introduced to regulate surrogacy procedures.[11] The Bill provided for the registration of surrogacy clinics, defined eligibility criteria of commissioning couples and surrogates, and set up National and State Boards to advise the government on surrogacy policies. This Bill was referred to the Standing Committee on Health

and Family Welfare, which made certain recommendations.[1] However, with the dissolution of the 16th Lok Sabha, the Bill lapsed and another Bill was introduced to replace it in 2019.[3] This Bill was referred to a Select Committee of Rajya Sabha.[4]

While examining the Bills, both Committees noted that: (i) surrogacy procedures cannot be conducted without using assisted reproduction technologies (ART), and (ii) both surrogacy and other ART procedures are usually undertaken by the same clinics. Therefore, they recommended that a comprehensive legislation must first be introduced to regulate clinics providing ART services, while specific concerns around use of surrogacy procedures may be specified in a separate surrogacy law. Subsequently, the ART Bill, 2020 was introduced.

However, the Surrogacy and ART Bills included different provisions on regulation of clinics (based on whether they provide surrogacy or other ART procedures), specify a separate set of eligibility criteria for parties looking to conceive a child (based on whether they seek ART or surrogacy services), and list different penalties for the same offending conduct (e.g. sale of gametes). For example, clinics providing surrogacy procedures are granted a registration for three years, while clinics providing other ART services are granted a registration for five years. Similarly, a married couple who has been unable to conceive a child after one year of unprotected sex may access ART services but is required to wait for five years to commission surrogacy.

The ART Bill, 2020 was referred to the Standing Committee on Health and Family Welfare, which submitted its report in March 2021.[12] The Committee recommended constituting common registration authorities and Boards for regulating surrogacy and ART services. During passing of the ART Bill in Lok Sabha, several amendments were adopted, which address some of these concerns.

However, certain differences in the ART Bill, 2021 (as passed by Lok Sabha) and the 2019 Surrogacy Bill persist. Table 1 compares key provisions of the 2019 Surrogacy Bill and the ART Bill, 2021 (as passed by Lok Sabha). Both Bills are currently pending in Rajya Sabha.

Table 1: Comparison of the key provisions of the Surrogacy Bill, 2019 and the ART Bill, 2021

	Surrogacy (Regulation) Bill, 2019 (as passed by Lok Sabha)	ART Bill, 2021 (as passed by Lok Sabha)
Infertility	▪ Infertility is defined as inability to conceive after five years of unprotected sex. Married couples must prove infertility to access surrogacy.	▪ Infertility is defined as the inability to conceive after one year of unprotected sex. Married couples must be infertile to access ART.
Regulation	▪ **Framework**: The central and the state governments will constitute National and State Surrogacy Boards. The functions of the National Board include advising the central government on policy matters and supervising the functioning of State Boards. ▪ **Registration**: Appropriate Authorities at the national and state level will regulate registration of clinics. ▪ Registration must be granted within 90 days and will be valid for a period of three years.	▪ **Framework**: National and State Surrogacy Boards under the 2019 Surrogacy Bill will act as the Boards under the ART Bill. These will be called National Assisted Reproductive Technology Surrogacy Board and State Assisted Reproductive Technology Surrogacy Board. ▪ **Registration**: The central government will appoint Appropriate Authorities (called the Appropriate Assisted Reproductive Technology and Surrogacy Authority) which will regulate the registration of clinics for both surrogacy and ART services (includes banks). The Authorities will be constituted at national and state level. ▪ The Appropriate Authority must report all registrations to the State Board. Registration will be granted only after the State Board inspects the premises. ▪ Registration must be granted within 30 days (or will be deemed granted) and will be valid for five years.
Eligibility to commission	▪ Indian couples: (i) where the woman is 23-50 years old and the man is 26-55 years old, (ii) married for at least five years, and (iii) with no surviving biological, adopted or surrogate children.	▪ Commissioning couples woman is between 21-50 years and the man is between 21-55 years. ▪ Single women may avail ART services. ▪ Foreigners are not prohibited from availing ART services.
Offences	▪ Punishes acts (e.g. selling gametes) with imprisonment of up to 10 years and fine of up to Rs 10 lakh. ▪ Any other violation by a surrogacy practitioner or clinic owner attracts imprisonment of up to 5 years with fine, with higher penalties for subsequent offences. ▪ Imprisonment up to 3 years with fine, if no penalty set out. ▪ Any person may directly file a complaint (with notice of at least 15 days to the appropriate authority). ▪ Offences are non-bailable.	▪ Prohibits similar acts with fine of Rs 5-10 lakhs. Subsequent violations attract imprisonment of 3-8 years, along with fine of Rs 10-20 lakh. ▪ Similar punishment (as above) applies to those offences where no penalty is specified. ▪ Complaint to court may only be made by the National Board, the State Board or its authorised officer. ▪ Offences are bailable.

	Surrogacy (Regulation) Bill, 2019 (as passed by Lok Sabha)	ART Bill, 2021 (as passed by Lok Sabha)
Seizure	▪ Only the registration authority may enter premises, search clinics and seize documents.	▪ The National/State Board and the National Registry have the powers to search premises and seize documents.
Storage	▪ 25 years or such other prescribed period.	▪ At least 10 years; then records transferred to the Registry.

Sources: The Surrogacy (Regulation) Bill, 2019; ART Bill, 2021 (as passed by Lok Sabha); Reports of the Standing Committee and Select Committee; PRS.

Note that a draft version of the ART Bill (2014) recognised surrogacy as an arrangement carried out through ART techniques and contained common provisions on regulation of clinics, provided for age-related eligibility criteria of the commissioning parties and donors, and specified common offences and penalties.[13] In addition, the Bill contained a separate section with provisions on surrogacy arrangements. That Bill was not introduced in Parliament.

Provisions on data sharing may violate the right to privacy of parties

Clauses 11, 21(e), (j), 23(b)

The Bill sets up a National Registry to act as a central database of all ART clinics and banks in the country. ART clinics and banks are required to share certain information with the Registry. This includes information related to: (i) enrolment of the commissioning parties and donors, (ii) procedures being undertaken, and (iii) outcome of the procedure and complications. This may imply disclosure of personally identifiable information of the parties (such as their names and other identity details). Further, they are required to share certain information upon establishment of the Registry. This includes: (i) the progress of the commissioning parties, and (ii) the number of donors screened, maintained and supplied. The National Registry is required to share this data with the National Board for the purpose of research and policy formulation. The requirement of ART clinics and banks to share personal information of the donors and the commissioning parties with the National Registry may violate the right to privacy of such individuals.

The Supreme Court has interpreted the Constitution to include the right to privacy as a fundamental right.[14] It states that this right may be infringed if: (i) there is a law, (ii) the law achieves a public purpose, and (iii) the public purpose is proportionate to the violation of privacy. The Bill does not specify the purpose of collecting personal information and sharing it with the Registry. While examining the Surrogacy Bill, the Standing Committee noted the need for a registry of surrogates, and surrogacy clinics and banks to: (i) effectively regulate and monitor surrogacy procedures, and (ii) track the number of times a woman acts as a surrogate or a donor donates their gamete for surrogacy.[1]

The ART Bill restricts the number of times an egg donor may donate her eggs to once in her lifetime. So, it may be necessary to keep track of egg donors. However, it is unclear why the personal details of all other parties to the procedure are required. Further, the National Registry may share such information (including personal information) with the National Board for the purposes of policy formulation and identifying new research areas. While anonymised statistics may be useful for policy formulation, it is unclear why personal information about the parties would be needed to achieve this. Note that currently medical practitioners are prohibited from disclosing the details of a patient learnt during their work, except in certain cases. These include if the disclosure is: (i) mandated by a court order, or (ii) due to a serious and identified risk to a specific person/community.[15]

The Standing Committee when examining the ART Bill had 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.[12] 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 *Puttaswamy-I* judgement, the Personal Data Protection Bill, 2019, and the National Digital Health Blueprint issued by the Ministry of Health and Family Welfare.

Mandatory collection of Aadhar details by ART banks may violate Supreme Court judgement

Clause 27(6)

The amendments adopted during the debate in Lok Sabha specify that ART banks must collect certain information of the donor including name, address and Aadhar number. This may violate the Supreme Court's *Puttaswamy-II judgement*.[16] In its judgement, the Court had ruled that the Aadhaar card/number may only be made mandatory for expenditure on a subsidy, benefit or service incurred from the Consolidated Fund of India. The Bill does not provide for any such benefit or service.

No provisions for counselling and withdrawal of consent of donors

Clause 21(c)

Under the Bill, ART clinics are required to provide counselling services to the commissioning parties on: (i) the chances of success of ART procedures in the clinics, and (ii) advantages and disadvantages of the procedures,

among others. The Bill does not contain similar provisions on counselling for donors. This differs from the current process. The ICMR guidelines on ART (2005) and on biomedical research (2006) require doctors to provide counselling to donors before administering a procedure (including counselling with respect to risks associated with ovarian hyperstimulation resulting from egg donation).[2,17] Similar provisions were contained in the draft version of the ART Bill (2014).[13] The 2014 Bill required the National Board to list the duties of a counsellor with special reference to the egg donor to explore the possible long-term effects of donations on her, to evaluate her psychological risks, and effects of donation on her existing relationships.

Further, commissioning parties are allowed to withdraw consent before the embryo or gamete is transferred to the woman's uterus. Donors have not been given similar rights to withdraw their consent. Both the ICMR guidelines (2006) and the 2014 Bill allowed donors to withdraw their consent at any time before implantation of the embryo or gamete in the woman's uterus.[17] Similarly, in the UK, the donor is permitted to withdraw consent before the embryo or gamete is used in treatment.[18]

Power of appropriate government to issue directions

Clause 38

The Bill empowers the central and state government to issue binding directions on questions of policy to the National Board/Registry/registration authority in union territories, and to the State Board/registration authority in states, respectively. These directions may be issued in the interests of "the sovereignty and integrity of India, security of the State, friendly relation with foreign States, public order, decency or morality". It is difficult to contemplate situations where the policy on ART would have linkages to issues of national security.

Note that similar provisions on the power to issue directions on policy matters exist in other regulatory laws, such as the Competition Act, 2002, the SEBI Act, 1992, and the National Medical Commission Act, 2019. However, those laws do not link these powers to other grounds such as state security or public order.

Additional eligibility criteria for ART may be set by regulations

Clause 21(a)

The Bill specifies various eligibility conditions for couples intending to undertake ART services. The Bill states that clinics must offer ART services only to married couples or single women, where the woman is between 21 and 50 years of age, and the man is between 21 and 55 years of age. In addition, married couples looking to access ART services must be infertile, i.e. unable to conceive after one year of unprotected coitus or suffer from any other proven medical condition which prevents conception. Further, the Bill specifies that ART banks may obtain semen from males between 21-55 years of age, and eggs from females between 23-35 years of age.

The Bill allows the central government to prescribe additional eligibility conditions for intending couples, women and donors through rules. The question is whether core features such as eligibility conditions should be specified in the parent law (and any modifications require an amendment of the law by Parliament) or whether they may be delegated to rule-making by the government.

Appeal procedure for commissioning parties not clear

Clause 19

Chapter III of the Bill specifies provisions for registration of ART clinics and ART banks. It details the procedures for grant, renewal and cancellation of registration by state government-appointed appropriate authorities. One of the provisions in the chapter provides for appeals against orders of rejection, suspension or cancellation of registration passed by the appropriate authorities. However, this provision allows appeals by the clinics as well as the commissioning parties. It is not clear as to why such appeals are allowed by the commissioning parties.

Other issues highlighted by the Standing Committee

- **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.

Annexure

Table 2: International comparison of ART laws

Country	India	United Kingdom	South Africa	Canada	Australia (Victoria)
Payment to the donor	▪ Medical expenses and insurance coverage.	▪ Reasonable medical expenses.	▪ Reasonable expenses	▪ Reimbursements include for travel and counselling.	▪ Reasonable expenses
Age of commissioning party	▪ Male between 21-55 ▪ Female between 21-50	▪ Not specified	▪ At least 18 years of age	▪ Not specified.	▪ Not specified.
Marriage needed to commission ART	▪ Marriage required, but single women allowed.	▪ No requirement.	▪ No requirement.	▪ No requirement.	▪ No requirement.
Medical reason to commission ART	▪ Couples must prove infertility.	▪ Not specified.	▪ Not specified.	▪ Not specified.	▪ If woman cannot conceive/carry child to term without treatment, or the woman/her partner risks transmitting a genetic abnormality.
Age of donor	▪ Male between 21-55 ▪ Female between 23-35, with at least one child (minimum 3 years old).	▪ Male between 18-45 years. ▪ Female between 18-35 years (except in certain cases)	▪ At least 18 years old. ▪ Exception made in case of a medical indication.	▪ At least 18 years old ▪ Exception made for preservation of own gamete.	▪ At least 18 years old ▪ Exception made if there is a risk of the child becoming infertile before adulthood.
Restrictions on donors	▪ Only one donation for an egg donor (with up to 7 eggs retrieved).	▪ Not more than 10 families per donor.	▪ Not more than six births using donor gametes.	▪ Not specified.	▪ Donated gametes cannot be used to produce more than 10 families.

Sources: **India:** The Assisted Reproductive Technology (Regulation) Bill, 2020; **United Kingdom:** The Human Fertilisation and Embryology Act, 2008; Code of Practice, 2019; **South Africa:** National Health Act, 2003; Regulations Relating to Artificial Fertilisation of Persons, 2012; **Canada:** Assisted Human Reproduction Act, 2004; Reimbursement Related to Assisted Human Reproduction Regulations; Consent for Use of Human Reproductive Material and In Vitro Embryo Regulations; **Australia (Victoria)**: The Assisted Reproductive Treatment Act, 2008; The Prohibition of Human Cloning for Reproduction Act, 2008; PRS.

1. Report No. 102: Surrogacy (Regulation) Bill, 2016, Standing Committee on Health and Family Welfare, August 10, 2017.
2. National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India, Indian Council of Medical Research, 2005.
3. The Surrogacy (Regulation) Bill, 2019.
4. 'Report of the Select Committee on the Surrogacy (Regulation) Bill, 2019', Rajya Sabha, February 5, 2020.
5. The Assisted Reproductive Technology (Regulation) Bill, 2021, as passed by Lok Sabha on December 1, 2021.
6. Uncorrected debate of 2-3 pm, Lok Sabha, December 1, 2021.
7. Uncorrected debate of 3-4 pm, Lok Sabha, December 1, 2021.
8. Uncorrected debate of 4-5 pm, Lok Sabha, December 1, 2021.
9. Uncorrected debate of 5-6 pm, Lok Sabha, December 1, 2021.
10. The Adoption Regulations, 2017, Ministry of Women and Child Development, January 4, 2017.
11. The Surrogacy (Regulation) Bill, 2016.
12. Report No. 129 - the Assisted Reproductive Technology (Regulation) Bill, 2020, Standing Committee on Health and Family welfare, 2021.
13. The Assisted Reproductive Technology (Regulation), Bill, 2014.
14. Justice K. S. Puttaswamy and Ors. vs Union of India and Ors, AIR 2017 SC 4161.
15. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.
16. Justice K.S. Puttaswamy Vs. Union of India, Supreme Court, Writ Petition (Civil) 494 of 2012, September 26, 2018.
17. Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, 2006.
18. United Kingdom: The Human Fertilisation and Embryology Act, 2008; South Africa: National Health Act, 2003.