

Legislative Brief

Assisted Reproductive Technology (Regulation) Bill, 2020

The Bill was introduced in Lok Sabha on September 14, 2020 by the Minister of Health and Family Welfare.

It was referred to the Standing Committee on Health and Family Welfare on October 3, 2020. The Committee is expected to submit its report by April 1, 2021.

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Highlights of the Bill

- ◆ Assisted reproductive technologies (ART) refer to techniques that seek to obtain a pregnancy by handling a gamete (sperm or egg) outside the human body and transferring the gamete or fertilised embryo into the woman's uterus. These arrangements include in-vitro fertilisation (fertilising an egg in the lab), gamete donation, and surrogacy.
- ◆ The Bill allows married infertile couples and women up to a certain age to commission ART procedures. It also specifies age ranges for gamete donors. Egg donors must be married with a child who is at least three years old. Commissioning parties must insure egg donors against risks.
- ◆ National and State Boards will be set up for regulating ART services. Further, a National Registry with information of all ART clinics and banks will be established. ART clinics and banks will be required to share periodic information about donors and commissioning parties with the Registry, which may share this with the National Board.
- ◆ Sale or purchase of gametes will attract fine between Rs 5-10 lakhs. Subsequent offence will attract imprisonment of 8-12 years with fine.

Key Issues and Analysis

- ◆ There are different Bills in Parliament to regulate surrogacy and ART procedures. These Bill provide for different registration procedures for clinics and specify different age-related eligibility criteria for commissioning parties. While there may be a need to regulate certain aspects of surrogacy arrangements separately, it is unclear why the two Bills differ on these common aspects of registration and eligibility.
- ◆ The Bill requires ART clinics and banks to share information about the commissioning parties and donors with the National Registry. The Registry may further share this information with the National Board. Sharing of this information may violate the right to privacy of parties.
- ◆ The Bill requires an egg donor to be a married woman with a child who is at least three years old. Further, donors are not required to be counselled with respect to the risks they may face while donating their gametes. This varies from the provisions of current guidelines on ART.
- ◆ The Bill specifies eligibility conditions that need to be fulfilled by the intending couple in order to commission ART procedures. Further, it allows additional conditions to be prescribed by Rules to be issued by the government. It may be questioned whether it is appropriate to delegate such conditions to be expanded by Rules.

PART A: HIGHLIGHTS OF THE BILL

Context

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. The guidelines specify separate provisions on citizenship of surrogate mothers, and compensation for surrogates.

In 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 referred to a Select Committee of the Rajya Sabha.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 on September 14, 2020. The Bill was referred to the Standing Committee on Health and Family Welfare on October 3, 2020.

Key Features

- **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:** 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 to facilitate registration of clinics and banks. 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.
- **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 recommendations, policies, and regulations of the National Board.
- **Eligibility criteria for commissioning parties:** ART services can be commissioned by married couples or women where: (i) the woman is above the legal age of marriage and up to 50 years, and (ii) the man is above the legal age of marriage and up to 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 can obtain semen from males between 21 and 55 years of age, and eggs from females between 23 and 35 years of age. An egg 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 eggs only once in her life and not more than seven eggs can be retrieved from her. A bank cannot 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 may only be carried out 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 eight and twelve years, and a fine between 10 and 20 lakh rupees.
- A court will take cognisance of an offence only on a complaint made by the National or State Board.

KEY ISSUES AND ANALYSIS

Overlap in the regulation of surrogacy services and other ART services

In 2016, a Bill was introduced to regulate surrogacy procedures.⁵ 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 Bills contain 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 can access ART services but is required to wait for five years to commission surrogacy.

Note that some of the provisions of the ART Bill with respect to the eligibility criteria of the commissioning parties are consistent with the recommendations of the Committees which examined the Surrogacy Bill. For example, the Standing Committee that examined the Surrogacy Bill, 2016 recommended reducing the required period of infertility to one year, and both Committees recommended allowing women (widows or divorcees) to access surrogacy services. However, the Bill does not fully incorporate the Committees' recommendations in other respects. For example, the Standing Committee had recommended that the eligibility to access surrogacy should be broadened to include live-in couples.¹ The Committee had stressed that the Supreme Court had given legal sanctity to live-in couples. This Bill allows ART services to be accessed by 'women' but does not include live-in couples.

Since this Bill was introduced after the recommendations of the Committees, it may be appropriate to make relevant changes to bring both the Surrogacy Bill and the ART Bill in harmony. Table 1 below summarises the key differences between the two Bills.

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.⁶ In addition, the Bill contained a separate section with provisions on surrogacy arrangements. That Bill was not introduced in Parliament.

Table 1: Comparison of the key provisions of the Surrogacy Bill, 2019 and the ART Bill, 2020

	Surrogacy (Regulation) Bill, 2019 (passed by Lok Sabha)	ART Bill, 2020
Infertility	<ul style="list-style-type: none"> Infertility is defined as inability to conceive after 5 years of unprotected sex. Married couples must prove infertility to access surrogacy. 	<ul style="list-style-type: none"> Infertility is defined as the inability to conceive after one year of unprotected sex. Married couples must be infertile to access ART.
Regulation	<ul style="list-style-type: none"> 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: Clinics are required to register with an authority comprising an officer of at least the rank of Joint Director of Health Department (as Chairperson) and a medical practitioner. Registration must be granted within 90 days and is valid for a period of three years. 	<ul style="list-style-type: none"> Framework: National and State Boards under the Surrogacy Bill will act as the Boards under the ART Bill. The Bill also provides for a National Registry with details of all ART clinics and banks in India. Registration: ART clinics and banks must register under the National Registry through similarly constituted registration authorities. The authority must report registration to the State Board. Registration may only be granted after the State Board inspects the premises. Registration must be granted within 30 days (or will be deemed granted) and is valid for five years.
Eligibility to commission	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Commissioning couples (of the legal age to marry) where woman is below 50 years and the man is below 55 years. Single women can avail ART services. Foreigners are not prohibited from availing ART services.
Offences	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> Prohibits similar acts with fine of Rs 5-10 lakhs. Subsequent violations attract imprisonment of 8-12 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.
Seizure	<ul style="list-style-type: none"> Only the registration authority may enter premises, search clinics and seize documents. 	<ul style="list-style-type: none"> The National/State Board and the National Registry have the powers to search premises and seize documents.
Storage	<ul style="list-style-type: none"> 25 years or such other prescribed period. 	<ul style="list-style-type: none"> At least 10 years; then records transferred to the Registry.

Sources: The Surrogacy (Regulation) Bill, 2019; ART Bill 2020; Reports of the Standing Committee and Select Committee; PRS.

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.⁷ 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 can 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.⁸

Eligibility criteria of egg donors may be restrictive

Clause 27(4) The Bill defines an egg donor as an ever-married woman, between the ages of 23-35 years, and having at least one live child of her own with a minimum age of three years. While the age restrictions may be correlated with improving the chances of obtaining a healthy and viable egg from the donor, it is unclear why the donor must be married or have an existing child of a minimum age.² Note that the Indian Council of Medical Research guidelines on ART (2005) only imposed an age restriction on women donors, i.e. to be 18-35 years of age to donate.² This is similar to the restriction imposed in the UK.⁹ In South Africa, the only restriction is for donors to be at least 18 years old.⁹

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).^{2,10} Similar provisions were contained in the draft version of the ART Bill (2014).⁶ 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.^{6,10} Similarly, in the UK, the donor is permitted to withdraw consent before the embryo or gamete is used in treatment.⁹ However, such provisions are not specified in the ICMR guidelines on ART (2005).²

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 can offer ART services only to married couples or single women above the legal age of marriage and: (i) where the woman is up to 50 years old, and (ii) the man is up to 55 years old. Married couples looking to access ART services must additionally 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 can obtain semen from males between 21-55 years of age, and eggs from females between 23-35 years of age. An egg donor should be an "ever-married" woman with at least one live child of her own (who is at least three years old).

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 registration authorities. One of the provisions in the chapter provides for appeals against orders of rejection, suspension or cancellation of registration passed by the registration authorities. However, this provision allows appeals by the clinics as well as the commissioning parties. It is not clear as to why registration-related appeals are allowed by the commissioning parties.

Annexure: International comparison of ART laws

Table 2 compares the Bill with the laws in some other countries which regulate ART procedures.

Table 2: International comparison of ART laws

Country	India	United Kingdom	South Africa	Canada	Australia (Victoria)
Payment to the donor	<ul style="list-style-type: none"> Medical expenses and insurance coverage. 	<ul style="list-style-type: none"> Reasonable medical expenses. 	<ul style="list-style-type: none"> Reasonable expenses 	<ul style="list-style-type: none"> Reimbursements include for travel and counselling. 	<ul style="list-style-type: none"> Reasonable expenses
Age of commissioning party	<ul style="list-style-type: none"> Male between 21-55 Female between 18-50 	<ul style="list-style-type: none"> Not specified 	<ul style="list-style-type: none"> At least 18 years of age 	<ul style="list-style-type: none"> Not specified. 	<ul style="list-style-type: none"> Not specified.
Medical reason to commission ART	<ul style="list-style-type: none"> Couples must prove infertility. 	<ul style="list-style-type: none"> Not specified. 	<ul style="list-style-type: none"> Not specified. 	<ul style="list-style-type: none"> Not specified. 	<ul style="list-style-type: none"> If woman cannot conceive/carry child to term without treatment, or the woman/her partner risks transmitting a genetic abnormality.
Marriage needed to commission ART	<ul style="list-style-type: none"> Marriage required, but single women allowed. 	<ul style="list-style-type: none"> No requirement. 	<ul style="list-style-type: none"> No requirement. 	<ul style="list-style-type: none"> No requirement. 	<ul style="list-style-type: none"> No requirement.
Age of donor	<ul style="list-style-type: none"> Male between 21-55 Female between 23-35, with at least one child (minimum 3 years old). 	<ul style="list-style-type: none"> Male between 18-45 years. Female between 18-35 years (except in certain cases) 	<ul style="list-style-type: none"> At least 18 years old. Exception made in case of a medical indication. 	<ul style="list-style-type: none"> At least 18 years old Exception made for preservation of own gamete. 	<ul style="list-style-type: none"> At least 18 years old Exception made if there is a risk of the child becoming infertile before adulthood.
Restrictions on donors	<ul style="list-style-type: none"> Only one donation for an egg donor (with up to 7 eggs retrieved). 	<ul style="list-style-type: none"> Not more than 10 families per donor. 	<ul style="list-style-type: none"> Not more than six births using donor gametes. 	<ul style="list-style-type: none"> Not specified. 	<ul style="list-style-type: none"> 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. '[Surrogacy \(Regulation\) Bill, 2016](#)', Report No. 102, 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 Surrogacy \(Regulation\) Bill, 2016](#).
6. [The Assisted Reproductive Technology \(Regulation\), Bill, 2014](#).
7. Justice K. S. Puttaswamy and Ors. vs Union of India and Ors, AIR 2017 SC 4161.
8. [Indian Medical Council \(Professional Conduct, Etiquette and Ethics\) Regulations, 2002](#).
9. United Kingdom: [The Human Fertilisation and Embryology Act, 2008](#); South Africa: [National Health Act, 2003](#).
10. [Ethical Guidelines for Biomedical Research on Human Participants](#), Indian Council of Medical Research, 2006.

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