Legislative Brief The Surrogacy (Regulation) Bill, 2016

Highlights of the Bill

- Surrogacy is an arrangement whereby an intending couple commissions a surrogate mother to carry their child.
- The intending couple must be Indian citizens and married for at least five years with at least one of them being infertile. The surrogate mother has to be a close relative who has been married and has had a child of her own.

years

- No payment other than reasonable medical expenses can be made to the surrogate mother. The surrogate child will be deemed to be the biological child of the intending couple.
- Central and state governments will appoint appropriate authorities to grant eligibility certificates to the intending couple and the surrogate mother. These authorities will also regulate surrogacy clinics.
- Undertaking surrogacy for a fee, advertising it or exploiting the surrogate mother will be punishable with imprisonment for 10 years and a fine of up to Rs 10 lakh.

Key Issues and Analysis

- The Bill permits surrogacy only for couples who cannot conceive a child. This procedure is not allowed in case of any other medical conditions which could prevent a woman from giving birth to a child.
- The Bill specifies eligibility conditions that need to be fulfilled by the intending couple in order to commission surrogacy. Further, it allows additional conditions to be prescribed by regulations. This may be excessive delegation of legislative powers.
- The surrogate mother and the intending couple need eligibility certificates from the appropriate authority. The Bill does not specify a time limit within which such certificates will be granted. It also does not specify an appeal process in case the application is rejected.
- The surrogate mother must be a 'close relative' of the intending couple. The Bill does not define the term 'close relative'. Further, the surrogate mother (close relative) may donate her own egg for the pregnancy. This may lead to negative health consequences for the surrogate baby.
- For an abortion, in addition to complying with the Medical Termination of Pregnancy Act, 1971, the approval of the appropriate authority and the consent of the surrogate mother is required. The Bill does not specify a time limit for granting such an approval. Further, the intending couple has no say in the consent to abort.

The Bill was introduced in Lok Sabha on November 21, 2016 by the Minister of Health and Family Welfare, Mr. J. P. Nadda.

It was referred to the Standing Committee on Health and Family Welfare on January 12, 2017. The Committee is expected to submit its report by July 11, 2017.

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PART A: HIGHLIGHTS OF THE BILL

Context

Surrogacy is the practice whereby one woman carries the child for another with the intention that the child should be handed over after birth.¹ Such a surrogacy arrangement may be altruistic or commercial in nature. Altruistic surrogacy involves an arrangement where the couple does not pay the surrogate mother any compensation other than the medical and insurance expenses related to the pregnancy. Commercial surrogacy includes compensation (in cash or kind) paid to the surrogate mother, which exceeds the reasonable medical expenses associated with the pregnancy. Currently, commercial surrogacy is allowed for Indian citizens.

In 2005, the Indian Council of Medical Research (ICMR) issued guidelines to regulate surrogacy arrangements.² The guidelines stated that the surrogate mother would be entitled to monetary compensation, the value of which would be decided by the couple and the surrogate mother. The guidelines also specified that the surrogate mother cannot donate her own egg for the surrogacy and that she must relinquish all parental rights related to the surrogate child.

In 2008, the Supreme Court of India in the Baby Manji Yamada vs. Union of India case highlighted the lack of regulation for surrogacy in India.³ In 2009, the Law Commission of India observed that surrogacy arrangements in India were being used by foreign nationals, and the lack of a comprehensive legal framework addressing surrogacy could lead to exploitation of poor women acting as surrogate mothers.⁴ Further, the Law Commission recommended prohibiting commercial surrogacy, allowing altruistic surrogacy and enacting a law to regulate matters related to surrogacy. In 2015, a government notification prohibited surrogacy for foreign nationals.⁵ The Surrogacy (Regulation) Bill, 2016 was introduced in Lok Sabha on November 21, 2016.

Key Features

Purposes for which surrogacy is permitted

- The Bill prohibits commercial surrogacy, and allows altruistic surrogacy. Altruistic surrogacy does not involve any monetary compensation to the surrogate mother other than the medical expenses and insurance coverage during the pregnancy. Commercial surrogacy includes surrogacy or its related procedures undertaken for a monetary benefit or reward (in cash or kind) exceeding basic medical expenses and insurance coverage.
- The Bill permits surrogacy when it is: (i) for intending couples who suffer from proven infertility; (ii) altruistic; (iii) not for commercial purposes; (iv) not for producing children for sale, prostitution or other forms of exploitation; and (v) for any other condition or disease specified through regulations.

Eligibility criteria for the intending couple and the surrogate mother

- The intending couple should have a 'certificate of essentiality' and a 'certificate of eligibility' issued by the appropriate authority. The surrogate mother too needs a 'certificate of eligibility'.
- A certificate of essentiality will be issued to the intending couple upon fulfilment of the following conditions: (i) a certificate of proven infertility of either or both of them; (ii) an order of parentage and custody of the surrogate child passed by a Magistrate's court; and (iii) insurance coverage for the surrogate mother.
- The certificate of eligibility to the intending couple is issued upon the fulfilment of the following conditions: (i) the couple being Indian citizens and married for at least five years; (ii) between 23 to 50 years old (wife) and 26 to 55 years old (husband); (iii) they do not have any surviving child (biological, adopted or surrogate), except if the child is mentally or physically challenged or suffers from a life threatening disorder; and (iv) such other conditions that may be specified through regulations.
- To obtain a certificate of eligibility from the appropriate authority, the surrogate mother has to: (i) be a close relative of the intending couple; (ii) be an ever married woman having a child of her own; (iii) be 25 to 35 years old; (iv) not have been a surrogate mother earlier; and (iv) have a certificate of medical and psychological fitness.

Parentage and abortion of surrogate child

- A child born out of a surrogacy procedure will be deemed to be the biological child of the intending couple.
- An abortion of the surrogate child requires the written consent of the surrogate mother and the authorisation of the appropriate authority. Further, this authorisation will have to be compliant with the Medical Termination of Pregnancy Act, 1971.

Appropriate authority and registration of surrogacy clinics

- The central and state governments will appoint one or more appropriate authorities. The functions of the appropriate authority include: (i) granting, suspending or cancelling registration of surrogacy clinics; (ii) enforcing standards for surrogacy clinics; and (iii) investigating and taking action against complaints of breach of the Act. The appropriate authority comprises the Joint Director of the state Health Department, an officer of the state Law Department, a medical practitioner, and an eminent woman.
- Surrogacy clinics cannot undertake surrogacy or its related procedures unless they are granted registration by the appropriate authority. Clinics must apply for registration within a period of 60 days from the date of appointment of the appropriate authority. This application will be accepted or rejected within 90 days. No human embryo or gamete can be stored by a surrogacy clinic for the purpose of surrogacy.

National and State Surrogacy Boards

- The central and state governments shall constitute the National Surrogacy Board (NSB) and the State Surrogacy Boards (SSBs), respectively. Functions of the NSB include: (i) advising the central government on surrogacy policy; (ii) laying down the code of conduct of surrogacy clinics; and (iii) supervising the functioning of SSBs.
- Functions of the SSBs include: (i) monitoring the implementation of the provisions of the Act; and (ii) reviewing the activities of the appropriate authorities functioning at the state/union territory level.

Offences and penalties

• The Bill creates certain offences which include: (i) undertaking or advertising commercial surrogacy; (ii) exploiting the surrogate mother; and (iii) selling or importing human embryo or gametes for surrogacy. These offences will attract a penalty of 10 years and a fine of up to 10 lakh rupees.

PART B: KEY ISSUES AND ANALYSIS

Definition of 'infertility' restricted to failure to conceive

Under the Bill, 'infertility' is a condition that has to be proven by an intending couple, in order to be eligible to commission a surrogacy procedure. The Bill defines infertility as the *inability to conceive* after five years of unprotected coitus or other medical condition preventing a couple from conception. This definition does not cover all cases in which a couple is unable to bear a child.

For example, there may be medical conditions where the woman may *conceive* but is unable to carry a child through the period of the pregnancy, i.e., the period of nine months following the conception. This includes cases where an intending mother may be able to *conceive* a child, but may have multiple miscarriages that result in her inability to *bear* a child. There are also other medical conditions like multiple fibroids in the uterus, hypertension, and diabetes that affect successful pregnancies.⁶ Such persons will not be covered under the definition of 'infertility' proposed in the Bill and therefore will not be eligible to undertake altruistic surrogacy.

In other countries like Netherlands, South Africa and Greece, to be eligible for altruistic surrogacy, the medical conditions that permit altruistic surrogacy are broader (for a detailed comparison, see Table 1, page 6). These include, in addition to the inability to conceive, other medical conditions that affect the intending mother's ability to give birth.

Additional eligibility criteria for surrogacy may be set by regulations

Additional eligibility criteria for intending couples may be specified through regulations

The Bill specifies various eligibility conditions for couples intending to undertake surrogacy. For example, the couple is required to fulfil all of the following five conditions: (i) be Indian citizens; (ii) be married for at least five years; (iii) either member is infertile; (iv) have no surviving children (biological or adopted or surrogate), except if the child is mentally or physically challenged or suffers from a life threatening disorder; and (v) be in the age group of 23-50 years (wife) and 26-55 years (husband). The Bill allows the NSB to prescribe additional conditions that need to be fulfilled by the intending couple through regulations. The question is whether this is excessive delegation of legislative powers. It may be argued that all conditions that make persons eligible to commission a surrogacy should be specified in the parent law and not be delegated to regulations.

Clause 2(p); Clause 4(iii)(a) (I)

Clause

4(iii)(c)

(IV);

Clause

48 (a)

'Any other condition or disease' may be specified through regulations for undertaking surrogacy

Clause 4 (ii)(e) The Bill specifies the purposes for which a surrogacy procedure may be undertaken. Surrogacy may be undertaken if: (i) it is for altruistic purposes; (ii) either member of the couple suffers from infertility; (iii) not for commercial purposes; and (iv) not for producing children for sale or prostitution. Further, the Bill allows the NSB to prescribe through regulations 'any other condition or disease' for which surrogacy may be allowed. It is unclear what is implied by 'any other condition' i.e., whether it relates to only a medical condition or would be of any other nature.

Review and appeal procedure for surrogacy applications not specified

In order to initiate a surrogacy procedure, the surrogate mother and the intending couple are required to obtain certificates of eligibility and essentiality upon fulfilling various conditions from the relevant appropriate authorities. Clause However, the Bill does not specify a time limit by which the authority will grant these certificates. Further, the Bill 4 (iii) does not specify a review or appeal procedure in case the surrogacy applications are rejected.

Note that other laws such as the Transplantation of Human Organs and Tissues Act, 1994, and adoption related provisions of the Juvenile Justice (Care and Protection) Act, 2015 prescribe a time period within which an application will be processed. They also provide the procedure for review and appeal, in case such an application is rejected.

Issues related to the surrogate mother being a 'close relative'

'Close relative' not defined

The Bill specifies various conditions that need to be fulfilled by a surrogate mother in order to be eligible for a surrogacy procedure. Upon fulfilling these conditions, the surrogate mother may obtain an eligibility certificate from the appropriate authority. One of the conditions to be proved is that the surrogate mother is a 'close relative' of the intending couple who commission the surrogacy. However, the Bill does not specify who will be a 'close relative'.

Some other laws define terms such as 'relative' or 'near relative'. For example, the Transplantation of Human Organs and Tissues Act, 1994 specifies that a living donor has to be a 'near relative'. It defines a 'near relative' to include spouse, son, daughter, father, mother, brother or sister. The Companies Act, 2013 defines a 'relative' as: (i) members of a Hindu Undivided Family; (ii) husband and wife; or (iii) other relations prescribed under the Act.

Close relative can be the biological donor for the surrogate baby

Upon meeting eligibility conditions outlined in the Bill, a close relative can act as a surrogate or help in surrogacy by donating her egg or oocyte or otherwise. This provision differs from current surrogacy regulations. The current 4 (iii) (b) ICMR guidelines (2005) do not allow the surrogate mother to be an egg donor for the intending couple who have a surrogacy arrangement with her.⁷ Further, the Draft Assisted Reproductive Technology (Regulation) Bill, 2014 also Clause 2 stated that an egg donated by a relative of the couple seeking surrogacy must not be accepted by clinics.⁸

The surrogate mother being allowed to donate her egg as a part of the surrogacy arrangement may have adverse medical implications as the definition of 'close relative' is unclear. As per the Bill, the 'surrogate mother' is required to be genetically related to the intending couple. If a surrogate mother is a close relative of the male member of the intending couple (e.g., his sister), and is allowed to donate her egg for the surrogacy, it may result in congenital anomalies for the surrogate child. According to the World Health Organisation, when biological parents are related by blood, the prevalence of rare genetic congenital anomalies increases.⁹

Authorisation for termination of pregnancy

Approval for termination of pregnancy from the appropriate authority

Under the Bill, authorisation of the appropriate authority is mandatory for an abortion to be done during the period of Clause surrogacy. The authorisation also has to comply with the provisions of the Medical Termination of Pregnancy (MTP) 3 (vi); Act, 1971, which specifies the grounds for termination of pregnancy. However, the Bill does not specify the time Clause 9 period by which such authorisation for abortion has to be given.

Intending couple has no say in the consent to abort a surrogate child

Clause 3 (vi); Clause 9

An abortion of the surrogate child requires the written consent of the surrogate mother and an authorisation by the appropriate authority. The Bill further states that no person may force the surrogate mother to abort the foetus. However, after the birth, the child is considered the biological child of the intending couple and they are responsible for bringing up the child. If a child being born out of surrogacy arrangement is at the risk of physical or mental abnormalities, under the Bill only the surrogate mother's consent will be required to abort the child. The intending

Clause 4 (iii) (b) (II)

Clause

(I);

(ze)

couple will have no role in this decision. Under the provisions of the MTP Act, 1971, abortion in such cases is allowed with the consent of the 'pregnant woman'. The complexity in the case of surrogacy is that the surrogate mother (who is carrying the child) is different from the intending couple who has to bring up the child.

Presumption that the surrogate mother was compelled to be a surrogate

Clause 39 If a surrogate mother renders surrogacy services other than those permitted under the Bill, it shall be presumed that she was compelled to do so by: (i) her husband; (ii) the intending couple; or (iii) any other relative. They will be liable for abetting the offence of initiating commercial surrogacy. The burden of proof is on these parties to establish that they did not compel the surrogate mother. Further, the Bill does not define 'relative' for this purpose. It is unclear why the Bill seeks to reverse the burden of proof from the prosecution to the defendants.

Ordinarily, the burden of proof is on the prosecution to prove that a certain wrongful act was committed by the defendant, and not on the defendant to prove that he did not commit that act. In some laws where the burden of proof is reversed, there are typically some circumstantial conditions which the prosecution needs to prove in order for the court to presume that the defendant has committed the crime.¹⁰

Storage of embryo or gamete for surrogacy not allowed

The Bill prohibits storage of embryos and gametes (unfertilised egg and sperm) for the purpose of surrogacy. This differs from the current ICMR guidelines (2005) which allow the storage of embryos for a period of five years.² The prohibition on storage of egg or sperm may have adverse health implications for the intending mother.

Typically, for a surrogacy, the eggs are extracted from the intending mother and are implanted in the surrogate mother's uterus. The success rate of one implantation is below 30%, therefore, multiple implantation attempts may be required.¹¹ To ensure availability of eggs for the multiple attempts, extra eggs are extracted and stored. Note that the intending mother needs to undergo extensive hormonal treatment for this extraction. Repeated stimulation for extraction of eggs leads to the risk of Ovarian Hyperstimulation Syndrome (OHSS) for the intending mother. In some rare cases, OHSS may lead to complications like blood clots and kidney failure.¹²

http://www.hfea.gov.uk/docs/Warnock Report of the Committee of Inquiry into Human Fertilisation and Embryology 1984. pdf.

8. Draft Assisted Reproductive Technology (Regulation) Bill, 2014,

http://www.prsindia.org/uploads/media/draft/Draft%20Assisted%20Reproductive%20Technology%20(Regulation)%20Bill,%2020 14.pdf.

9. Fact sheet: Congenital anomalies, World Health Organisation, September, 2016, <u>http://www.who.int/mediacentre/factsheets/fs370/en/</u>.

Clause 3 (vii)

^{1.} Report of the Committee of Inquiry into Human Fertilisation and Embryology, United Kingdom, 1984,

^{2.} National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India, Indian Council of Medical Research, 2005, <u>http://icmr.nic.in/art/art_clinics.htm</u>.

^{3.} Baby Manji Yamada vs. Union of India and Another; (2008) 13 SCC 518.

^{4.} Need for Legislation to Regulate Assisted Reproductive Technology Clinics as well as Rights and Obligations of Parties to a Surrogacy, Report No. 228, Law Commission, 2009, <u>http://lawcommissionofindia.nic.in/reports/report228.pdf</u>.

^{5.} Instructions regarding commissioning of surrogacy, Ministry of Health and Family Welfare, November 4, 2015, http://www.icmr.nic.in/icmrnews/art/DHR%20notification%20on%20Surrogacy.pdf.

^{6.} Health problems in pregnancy, U.S. National Library of Medicine, https://medlineplus.gov/healthproblemsinpregnancy.html.

^{7.} Chapter 3, National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India, Indian Council of Medical Research, 2005, <u>http://icmr.nic.in/art/Chapter_3.pdf</u>.

^{10.} Rajeev Kumar vs. State of Haryana, AIR 2014 SC 227; Sanjiv Kumar vs. State of Punjab, (2009) 16 SCC 487.

^{11.} Chapter 1, National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India, Indian Council of Medical Research, 2015, <u>http://icmr.nic.in/art/Chapter%20_1.pdf</u>.

^{12.} Ovarian Hyperstimulation Syndrome, U.S. National Library of Medicine, https://medlineplus.gov/ency/article/007294.htm.

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Annexure: International comparison of surrogacy laws

Table 1 compares the Bill with the laws in some other countries which regulate surrogacy. These countries have fewer restrictions with regard to eligibility criteria for the intending parents and the surrogate mother, amongst others.

Table 1: International comparison of surrogacy laws

Country	India Surrogacy Bill, 2016	Netherlands	United Kingdom	South Africa	Greece	Russia
Type of surrogacy allowed	 Altruistic (Commercial surrogacy prohibited). 	 Altruistic (Commercial surrogacy prohibited). 	 Altruistic (Commercial surrogacy prohibited). 	 Altruistic (Commercial surrogacy prohibited). 	 Altruistic (Commercial surrogacy prohibited). 	 Commercial surrogacy allowed.
Payment to the surrogate	 Medical expenses and insurance coverage. 	 Reasonable expenses, insurance and legal charges. 	 Reasonable expenses. 	 Medical expenses and insurance coverage (including any loss of earnings to the surrogate). 	 Expenses related to pregnancy and post- partum period (including any loss of earnings to the surrogate). 	 No limit.
Legal guardian of the surrogate child	 Intending couple. 	 Surrogate (transfer of guardianship through adoption). 	 Surrogate (transfer of guardianship through adoption or order). 	 Intending parent(s). 	 Intending parent(s). 	 Surrogate, if it is her egg. Intending parent(s), otherwise.
Imprisonment for engaging in commercial surrogacy	 10 years. 	 Maximum one year. 	 Maximum three months. 	 Maximum 10 years. 	 Minimum two years. 	 No provision.
		Eligibility crit	teria for commissioning pa	rent(s)		
Existence of a medical reason	 Must prove infertility i.e., inability to conceive. 	 Congenital absence of a uterus or any other condition. 	 No requirement. 	 Not able to give birth to a child and such a condition is permanent. 	 Intending mother is unable (for medical reasons) to bear a child. 	 Gestation and birth of a child is impossible due to medical reasons.
Requirement of being married	 Yes. 	 No (single male/female allowed). 	 No (includes civil partnerships). 	 No (single male/female allowed). 	 No (single woman allowed). 	 No (single woman allowed).
		Eligibility	criteria for surrogate moth	her		
Relation to intending parent(s)	 Close relative. 	 No. 	■ No.	■ No.	■ No.	 No.
Age	 25-35 years. 	<44 years.	 Not specified. 	 Not specified. 	 Not specified. 	 20-35 years.
Requirement of being married	• Yes.	 No. 	 No. 	 No. 	• No.	 No.
No. of own children	 At least one. 	 At least one. 	 No requirement. 	 At least one. 	 No requirement. 	 At least one.
No. of times one can be a surrogate	 Once. 	 No restriction. 	 No restriction. 	 No restriction. 	 No restriction. 	 No restriction.
Consent of the partner	 No provision. 	 Not required. 	 Not required. 	 Required. 	 Required. 	 Required.

Sources: A comparative study on the regime of surrogacy in EU member states, European Parliament, 2013; India: The Surrogacy (Regulation) Bill, 2016; Netherlands: Dutch Society of Obstetrics and Gynaecology guidelines; United Kingdom: Surrogacy Arrangements Act, 1985; South Africa: Chapter 19, Children's Act, 2005; Greece: Article 1458 of the Greek Civil Code; Russia: Article 51-52, Family Code, 1995; Federal Law on the Fundamentals of Protection of Citizens' Health in Russian Federation 2011; PRS.