Views, Comments and Recommendations to the

Department Related to The Parliamentary Standing Committee on Health and Family Welfare

On

The Assisted Reproductive Technology [Regulation] Bill, 2020

By

Sama Resource Group for Women and Health

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THE ASSISTED REPRODUCTIVE TECHNOLOGY(REGULATION) BILL, 2020

Comments and Recommendations

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General:

There are overlaps in the Surrogacy (Regulation) Bill 2020 and the ART Bill 2020. The administrative, regulatory structures – The Surrogacy Bill 2020 and the ART Bill 2020 (in reference to the former) prescribe creation of administrative, regulatory structures and bodies at the National and State levels. National and State – are the same for both the Laws. The National Registry of the clinics is the same and registration of surrogates, donors are the same. Both ARTs and Surrogacy are interlinked to each other. Also there are overlaps in the Surrogacy Regulation Bill 2020 and the ART Bill 2020 in terms of the administrative, regulatory structures at the National and State levels.
It is recommended that these overlaps are examined and streamlined to ensure that overlaps are addressed for effective implementation.

CHAPTER I

PRELIMINARY

Ambiguities in the definitions and the clauses

Clause 2(1) (d): "assisted reproductive technology bank" *means an organisation that is set up to supply sperm or semen, oocytes or oocyte donors to the assisted reproductive technology clinics or their patients;*
Comment & Recommendation: The ART Bank cannot and ought not to be a place where oocyte donors can be '**supplied**' from.

Clause 2(1) g: "Commissioning Couple" *means an infertile* ***married couple*** *who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the services authorised of the said clinic or bank;*
Comment: Restricting it to only married couples is discriminatory and would be violative of the right to life and right to equality guaranteed to all persons under Articles 21 and 14 of the Constitution of India. Recognition and respect needs to be accorded to the reproductive right of each person to reproductive health and the right to form a family. The Supreme Court of India, very recently, ruled that, "*In the modern time, live-in relationship has become an acceptable norm. It is not a crime*." Even the children that are born to such couples are accepted as legitimate under the law. Moreover, single persons are eligible to adopt children under Indian law. Irrespective of marriage, the Bill should include everyone who wants to avail ARTs.
Recommendation: Therefore, the definitions stated herein should change to "any person, whether single, married, in a live-in-relationship, or a patient who is medically infertile or who due to a medical condition or by choice," approach the ART Clinic or ART Bank for treatment or supply of eggs or

sperms, respectively. Couples should also not imply a relationship between male and female persons as India has through several existing laws recognized the rights of transgender persons as well as LGBQI persons. The terms "couple" in the entire Act/Bill should change to "person/s". It should be for all persons who are desirous of having a child and/or desirous of donating gametes, etc.

In Definitions *Clause 2 (1) (x): "Woman" means any woman above the legal age of marriage* *who approaches an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the authorised services of the clinic or bank.*

Comment & Recommendation: It is better not to have such a definition on the legal age of marriage - as even though 18 years is the legal age, in some religions a lower age is acceptable. Besides, the lines are blur between age 17-19, and the case in which a young woman expired in Mumbai - as she had produced documents showing she is 18, but was actually 17 - and underwent a procedure of ART - and subsequently developed complications and died - makes out a case to put the minimum age for a "woman" approaching an ART centre for any procedure to be above 21 years of age. **A similar comment is for clause 21(g).**

Clause 5 (f) of Statement of Object and Reasons "*Commissioning couple and woman"* – *(Clause 5 (f)* and in some other places mentions ***"Commissioning couple, woman and a donor"*** *[Clause 21 (e)]".*
Recommendation: This should not be left to the Rules and there should be an uniformity in both the Bills related to ARTs and Surrogacy.

CHAPTER III

PROCEDURES FOR REGISTRATION

Clause 16, the Registration Authorities - National and State, should conduct regular inspections of the ART centres - to ensure that the standards are being met and they are following the law and rules at the ART Centre/ Bank/ etc. The Rules state they will act on a complaint, but they should do regular inspections too. Though, this could lead to corruption - as power is given in the hands of people - who may take advantage of the authority they have.
Recommendation: Some checks should be in place on the authority too - and all inspection reports, and minutes of meetings, etc. of the registration authorities and the Boards set up under the Act should be available in the public domain and on a website too, where it is easily accessible.
All proceedings of the Registration Authority should be recorded and available in the public domain and should be viewed by an independent authority or committee to check that the proceedings are being conducted properly and without any bias or corruption.

Clause 16(2) states that if the Authority fails to grant or reject, it should be deemed registration.
Recommendation: No deemed registration should be given, and the Registration.

CHAPTER II

AUTHORITIES TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY

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CHAPTER IV

DUTIES OF ASSISTED REPRODUCTIVE TECHNOLOGY CLINIC AND ASSISTED REPRODUCTIVE TECHNOLOGY BANK

Clause 5 (f): *to provide that the assisted reproductive technology clinics shall provide professional counselling to commissioning couple and woman about all the implications and chances of success of assisted reproductive technology procedures in the clinic; and they shall also inform the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy and any such other matter as may help the commissioning couple to arrive at an informed decision that would most likely be the best for the commissioning couple and woman;*
Recommendation: It is recommended to change this to "enable persons to arrive at an informed decision independently" and deletion of "that would most likely be the best for the commissioning couple and woman", given that the clinics have a conflict of interest in provision of services.

Similar **Clause 21 (c)(iii)** - states the clinics should help the commissioning couple or woman to arrive at an informed decision ... likely to be the best for the couple.
Recommendation: The clause should be amended to state that detailed information on risks, success rates, failure rates, benefits, etc. should be provided to the commissioning couple or woman so that

she/ they are able to make an informed decision. The clinic should not try and influence the decision by stating it is good or by highlighting the benefits. This clause should be amended.

Clause 21 (e)*: the clinics and banks shall ensure that information about the commissioning couple, woman and donor shall be kept confidential and the information about treatment shall not be disclosed to anyone except to the database to be maintained by the National Registry, in a medical emergency at the request of the commissioning couple to whom the information relates, or by an order of a court of competent jurisdiction;*
Recommendation: It is imperative that the data given to the National Registry is not misused, and that the data provided to them should be anonymous and unlinked. Further, the reasons for carrying out surrogacy or breaching confidentiality in cases of an emergency should be recorded in writing in the medical cases papers of the patient. This should be added to the clauses.

Further, if research is being carried out by the ART Clinic or ART Bank, they need to follow the rules and regulations with regard to research under the Drugs and Cosmetics Act and Rules, and other guidelines too.

Clause 21 (f) - **grievance cell at the clinic** - if no guideline is provided about the grievance cell and mechanism.

Recommendation: A grievance guidance document should be provided and the mechanism should be explained. District authority or ombudsman who accepts, investigates and decides on grievances in a time bound manner.

Clause 21 (g) *the clinics shall apply the assisted reproductive technology services,— (i) to a woman above the legal age of marriage and below the age of fifty years; (ii) to a man above the legal age of marriage and below the age of fifty-five years;*
Reference to the legal age of marriage should be revised to 18 years coinciding with "age of majority" for all persons.

Clause 27. (1) *The screening of gamete donors, the collection, screening and storage of semen; and provision of oocyte donor, shall be done only by a bank registered as an independent entity under the provisions of this Act.*
Comment & Recommendation: The Banks should be restricted to accepting and preserving eggs, sperms, etc. with adequate facilities for storage. The "bank" used in this Bill should mean a registered institution that receives and preserves / cryo-preserves sperm or semen, oocytes, towards providing these are required by registered ART clinics towards ART procedures.
Reference to the legal age of marriage should be revised to 18 years coinciding with "age of majority" for all persons.

Clause 22 (1) *The clinic shall not perform any treatment or procedure without— (a) the written consent of all the parties seeking assisted reproductive technology;*
Recommendation: The consent should be written and should be informed consent and not merely consent throughout the Bill. Informed consent that requires detailed information and explanation all the risks, alternatives, possible outcomes, procedures, costs, to enable an informed decision in a form and language that is understood by persons accessing ART services, including gamete donors. In all

subsequent sections, wherever consent has been referred to, it should be informed consent explained to the person/s before any kind of procedure.

Clause 22 (4) (ii) *"insurance" means an arrangement by which a company, individual or commissioning couple undertake to provide a guarantee of compensation for specified loss, damage, complication or death of oocyte donor during the process of oocyte retrieval;*
Recommendation: "Insurance" is not a company nor is it compensation. Insurance is the equitable transfer of risk of a loss from one entity to another in exchange for money. It therefore is a transfer of risk in money terms of an untoward incident that may take place.
The ART clinic and/or commissioning person should be required to pay for an insurance policy for the donor that would cover the risk of any untoward incident that may take place, including death. Further, in the case of **death separate compensation** should be paid.

Clause 22 (1)(b) - speaks of insurance - which is a good measure.
But, who will purchase the insurance policy - the clinic/ bank/ or the couple/ woman? How will it be assured that the costs of the insurance taken by the clinic/ bank are not pushed onto the donor or the recipient?
Recommendation: This should clear in the document. Oocyte retrieval is potentially harmful to the woman's health, a fact that the Bill itself recognises. Given this, the Bill must mandate counselling and written informed consent of the donor. While the Bill provides for insurance for the oocyte donor in case of damage or death during the process of retrieval, it should but does not specifically deal with the liability of banks and clinics in cases of negligence.

Clause 23 - Duties of assisted reproductive technology clinics and banks to keep accurate records.
Recommendation: It must reiterate the importance of maintaining confidentiality of the donors and the recipients - and any record that is shared by the registry or the Board should be anonymized. The full name documents should be kept in a safe and secure place, and any digital copy must ensure complete security so that there is no breach of confidentiality.

Clause 23 (b)(i): *(b) all clinics and banks shall, as and when the National Registry is established, submit by online, (i) all information available with them in regard to progress of the commissioning couple or woman;*
Recommendation: The information should be anonymised if it is merely for the purpose of monitoring the clinics and banks. Else, information / data submission has scope for misuse. If this is for research purposes then data / information should be submitted following receipt of written informed consent for the research. Necessary ethical safeguards based on guidelines for such research (referred earlier) must also be put in place and followed stringently.

While it should be mandatory for ART Clinics and ART Banks to report any untoward incident or problem that might occur before, during or after the ART procedure, as has been stated through grievance mechanisms in the Bill, however, reporting online entails risks and other safer methods and means should be followed.

Clause 23 (c): *the records maintained under clause (a) shall be maintained for at least a period of ten years, upon the expiry of which the clinic and bank shall transfer the records to a central database of the National Registry.*

Recommendation: Similarly, to be specified that the data so transferred should be anonymous unlinked data only.

Clause 23 The Registry, in turn, is to share the "data generated"" with the National Board for research and policy formulation.
Recommendation: Instead of sharing non-identifiable anonymised data, the necessity for sharing such granular information is unclear and raises concerns around couple, gamete donor confidentiality and privacy. Instead, information on individual clients and their treatment should remain decentralised with the respective clinics and banks, which should be mandated to safeguard it by following data security protocols and measures, with remedies provided in case of a breach. The Bill must also provide robust protections for couples, gamete donor data. Clinics and banks are supposed to provide all information pertaining to their enrolment, procedures, complications and outcomes to the national registry through a system of online submission.

Clause 24: While using human gametes and embryos, the duties to be performed by the clinics and banks shall be as under:—(*a*) the clinics shall harvest oocytes in such manner as may be specified by regulations;
Recommendation: Delete "harvest" replace with "retrieve" – the Bill has stated that no more than **seven oocytes** will be retrieved. The word harvest is misleading and implies a large number of oocyte retrieval and storage which should not be permitted. It maybe noted that the number of oocytes that can be retrieved should be restricted to very few (not more than seven as stated), as higher number of extraction of oocytes entails risk.

The woman should be provided complete information in this regard in advance as to how many oocytes will be retrieved from her, as well as possible adverse events or serious adverse events should also be told to her orally and in writing, prior to undertaking the procedure.

Clause 24 (b) *the number of oocytes or embryos that may be placed in the uterus of a woman during the treatment cycle shall be such as may be specified by the regulations;*
Recommendation: Currently the Bill only states that "Multiple embryo implantation needs to be regulated". There is no mention of the maximum number of oocytes that will be implemented expect "as may be specified by the regulations". It should be clearly stated that **no more than one embryo** will be implanted at a time.

Clause 25 - **Pre- implantation Genetic Diagnosis**
This section need to add clauses on research ethics, permission from the appropriate authorities as far as research is concerned, and following all procedures for genetic testing and treatment as are laid down in national and international rules and guidelines issued from time to time, including ICMR guidelines.

Clause 25 (1): *The Pre-implantation Genetic testing shall be used to screen the human embryo for known, pre-existing, heritable or genetic diseases or for such other purposes as may be prescribed.* ***(2)*** *The donation of an embryo after Pre-implantation Genetic Diagnosis to an approved research laboratory for research purposes shall be done only-— (a) with the approval of the commissioning couple or woman; and (b) when the embryo suffers from pre-existing, heritable, life-threatening or genetic diseases.*

(3) The National Board may lay down such other conditions as it deems fit in the interests of the Pre-implantation Genetic testing. Explanation.—For the purposes of this section, the expression— (i) "Pre-implantation Genetic Diagnosis" means the genetic diagnosis when one or both genetic parents has a known genetic abnormality and testing is performed on an embryo to determine if it also carries a genetic abnormality;

Clause 26 (3) *A person shall not knowingly provide, prescribe or administer anything that shall ensure or increase the probability that an embryo shall be of a particular sex, or that shall identify the sex of an in-vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.*

Recommendation: Use of pre-implantation genetic diagnosis to screen the embryo for pre-existing, heritable or genetic disease or as specified by the registration authority. Much caution needs to be taken before allowing and legalising such pre-implantation genetic diagnosis in the Bill. Such screening can lead to "made-to-order" or "tailor-made" babies. There are a lot of ethical issues attached to such screening, and the power given to the registration authority to allow such specified diseases gives scope for any and every disease to be included in the pre-screening, which could prove to be a dangerous trend. A public and larger discussion is required with diverse subject experts before such a provision is mandated in the law.

Clause 27 (1): *The screening of gamete donors, the collection, screening and storage of semen; and provision of oocyte donor, shall be done only by a bank registered as an independent entity under the provisions of this Act.*
Clause 27 (2) (c): *Examine the donors for such diseases, as may be prescribed.*
Recommendation: Given that the screening, examination of donors will require medical expertise, infrastructure, etc. the capacity of ART Banks to implement this needs more clarity and details – whether such procedures for screening, expertise is envisaged in ART Banks.

Clause 27 (4): *An oocyte donor shall be an ever married woman having at least one live child of her own with a minimum age of three years and to donate oocytes only once in her life and not more than seven oocyte shall be retrieved from the oocyte donor.*
Recommendation: The Bill prohibits unmarried women to become oocyte donors. Only married women with proven fertility can become surrogate mothers or donate their eggs. On the other hand, when it comes to semen donation there are no such restrictions on men. Further, single women, who maybe never married, or ever married (including divorcees, widows, separated women, etc.) should also be allowed to donate under the Bill. These restrictive clauses, which reflect the dominant patriarchal values of our society, need to be reconsidered in favour of respecting the autonomy and freedom of women's reproductive choices.

Clause 27 (5): *All unused oocytes shall be preserved by the banks for use on the same recipient, or given for research to an organisations registered under this Act after seeking written consent from the commissioning couple.*
Recommendation: Use of oocytes should be permitted only following the written consent of the oocyte donor for the purpose of research. This should be in addition to their consent for ART process.

Clause 27 (6): *A bank shall obtain all necessary information in respect of a sperm or oocyte donor, including the name, identity and address of such donor, in such manner as may be prescribed, and shall undertake in writing from such donor about the confidentiality of such information.*

Recommendation: This clause is unclear. It is imperative that the bank ensures confidentiality and safe storage of information of donors. All necessary protocols to ensure this must be clearly drafted and implemented. Any action contrary to such protocols must be addressed by stringent measures as part of the protocol.

Clause 30 (2): *The research on human embryos or gametes within India shall be performed in such manner as may be prescribed.*
Recommendation: This and several other important clauses in the Bill require details and currently merely state "as may be prescribed". It is critical for the ethical conduct of research as well as ART procedures that the details are provided and finalized following public deliberations and inputs from experts.

Clause 31 (1): *The child born through assisted reproductive technology shall be deemed to be a biological child of the commissioning couple and the said child shall be entitled to all the rights and privileges available to a natural child only from the commissioning couple under any law for the time being in force.*
Recommendation: As stated previously, all clauses that mention commissioning couple, must be replaced by commissioning parents with rights and privileges that accrue to the child.

Research should be kept separate and the rules and regulations from granting research to a clinic or an organization need to be strict so that there is adherence of the highest standards and there is no abuse or misuse of the license given to the clinic for research. Very often research is conducted without regard to ethics, and is conducted on the poor, vulnerable, illiterate population, so that the researchers can get away with it without taking informed consent and without providing adequate compensation. Therefore, medical research requires extra ethical guidelines before permission or accreditation is given to any ART centre or clinic, etc.

CHAPTER V

OFFENCES AND PENALTIES

Clause 35 Under offences and procedures - clause 35 speaks of a complaint only from the Boards.
Recommendation: Any person who has accepted the services of the clinic or their heirs should be allowed to file a complaint with the courts directly too. The clause should be amended.

CHAPTER VI

MISCELLANEOUS

Clause 46 (3):*The cryopreservation of sperm, oocytes and embryo by the ART Banks need to be regulated and the proposed legislation intends to make Pre Genetic Implantation Testing* ***mandatory*** *for the benefit of the child born through assisted reproductive technology.*
Recommendation: Making pre-implantation genetic diagnosis mandatory in the name of the child born is extremely problematic and unethical. Such screening is premised eugenic considerations and allows for misuse – and concerns of "designer babies".

STATEMENT OF OBJECTS AND REASONS

Statement of objects and reasons speaks of Indian being a global fertility industry - but the provisions are restricting the facilities to only personal use and prohibiting use of the facilities within or outside the country too. The Act does not achieve the objects and reasons of the Act. If the object is to regulate the ART clinics, then regulation would be maintaining standards and procedures - not restricting transfers to clinics within India or outside India.