BILLS SUPPLEMENT

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Bill No. 33 Human Assisted Reproductive Technology Bill

2023

THE HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY BILL, 2023

MEMORANDUM

1. Policy and principles

The object of the Bill is to regulate the use of human assisted reproductive technology; to designate the Medical and Dental Practitioners Council as the body responsible for the administration of this Act; to provide for designation of health units as fertility centres; to provide for the establishment of sperm, oocyte and embryo banks within fertility centres; to regulate the donation and storage of gametes or embryos; to provide for the rights and duties of persons involved in human assisted reproductive technology and rights of children born through human assisted reproductive technology; to provide for a register for information collected on human assisted reproductive technology under this Act; and for related matters.

2. Justification for the Bill

Over time, there has been an increase in the number of people opting for human assisted reproductive technology through various fertility solutions, including the use of In Vitro Fertilisation treatment, commonly known as "IVF", intrauterine insemination, among others.

The increasing demand for the use of human assisted reproductive technology has been necessitated by the growing cases of primary and secondary infertility, and other health related challenges among persons seeking to have children. There is thus need to enact a law to protect persons seeking the human assisted reproductive technology services, providers of the services and children born through human assisted reproductive technology.

3. Remedies proposed by the Bill

The intention of the Bill is to address the gaps caused by the absence of a legal framework on human assisted reproductive technology in Uganda. The Bill therefore seeks to regulate human assisted reproductive technology in Uganda, provide for the designation of health units as fertility centres, provide for the establishment of sperm, oocyte and embryo banks within fertility centres, rights and duties of persons involved in human assisted reproductive technology and donation and storage of gametes and embryos. The Bill further seeks to protect the rights of a child born through human assisted reproductive technology.

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Tororo District.

THE HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY BILL, 2023

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A BILL for an ACT

ENTITLED

THE HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY ACT, 2023

The object of the Bill is to regulate the use of human assisted reproductive technology; to designate the Medical and Dental Practitioners Council as the body responsible for the administration of this Act; to provide for designation of health units as fertility centres; to provide for the establishment of sperm, oocyte and embryo banks within fertility centres; to regulate the donation and storage of gametes and embryos; to provide for the rights and duties of persons involved in human assisted reproductive technology and rights of children born through human assisted reproductive technology; to provide for a register for information collected on human assisted reproductive technology under this Act; and for related matters.

BE IT ENACTED by Parliament as follows:

PART I—PRELIMINARY

1. Application

This Act applies to—

(a) a man and woman who jointly seek to use human assisted reproductive technology to obtain a child; and

(b) a man and woman, where either the man or woman or both the man and woman, suffer primary or secondary infertility or health related challenges which affect the man or woman's ability to reproduce.

2. Interpretation

In this Act unless the context otherwise requires—

- "bank" means sperm, oocyte or embryo bank used for the storage and cryopreservation of sperm, oocyte and embryo;
- "child" means a person under the age of eighteen years;
- "Council" means the Medical and Dental Practitioners Council established under section 2 of the Medical and Dental Practitioners Act;
- "cryopreservation" means the process of slow freezing to preserve gametes at extreme low temperature;
- "currency point" means the value specified in relation to a currency point in the Schedule to this Act;
- "donor" means a person from whom a gamete is harvested or embryo is obtained, for use in human assisted reproductive technology;
- "embryo" means the biological organism resulting from the development of the human zygote, until eight completed weeks after fertilisation, equivalent to ten weeks of gestational age;
- "fertility centre" means a health unit designated under section 5 to offer human assisted reproductive technology services;

[&]quot;gamete" means a mature sperm or oocyte;

- "health unit" includes a private hospital, clinic, maternity centre or other specialised establishment as well as Government units of the same nature, licensed under the Medical and Dental Practitioners Act;
- "human assisted reproductive technology" means in vitro handling of sperms, oocytes and embryos for the purpose of reproduction;
- "human assisted reproductive technology service" means a service provided by a registered medical practitioner in a fertility centre for the purposes of human assisted reproductive technology;
- "infertility" means a condition characterised by the failure to establish a clinical pregnancy after twelve months of regular, unprotected sexual intercourse or due to a health challenge which affects a man or woman's capacity to reproduce;
- "intending parent" means a man and woman who enter into a surrogacy agreement with a woman for her to carry and give birth to a child for that man and woman;
- "Minister" means the Minister responsible for health;
- "oocyte" means a live human egg of the female germline at any stage of maturity;
- "parent" means the biological mother and father of a child or a man and woman who obtain a child through human assisted reproductive technology or surrogacy;
- "registered medical practitioner" means a medical practitioner who is registered under the Medical and Dental Practitioner's Act, duly qualified and certified by the Council to undertake human assisted reproductive technology services;

- "recipient" means a man and a woman who seek to use a donated gamete or embryo to obtain a child through human assisted reproductive technology but does not include a surrogate mother;
- "sperm" means a live human sperm of the male germline at any stage of maturity;
- "surrogacy" means a practice where a woman carries and gives birth to a child for another person;
- "surrogacy agreement" means an agreement between an intending parent and a surrogate mother where the surrogate mother agrees to carry a pregnancy and give birth to a child for the intending parent or until the pregnancy terminates; and
- "surrogate mother" means a woman who agrees to carry a pregnancy and give birth to a child for an intending parent.

PART II—ADMINISTRATION

3. Medical and Dental Practitioners Council

The Medical and Dental Practitioners Council established under the Medical and Dental Practitioners Act is responsible for the administration of this Act.

4. Functions of the Council

- (1) The Council is responsible for the regulation and supervision of the use of human assisted reproductive technology.
- (2) Without prejudice to the general effect of subsection (1), the Council shall—
 - (a) recommend to the Minister, health units for designation as fertility centres;
 - (b) recommend to the Minister, banks for approval;

- (c) enforce standards for fertility centres and banks prescribed under this Act;
- (d) inspect and monitor fertility centres and banks to ensure compliance with this Act; and
- (e) keep and maintain a register for human assisted reproductive technology in accordance with section 27.

PART III—DESIGNATION OF FERTILITY CENTRES AND
ESTABLISHMENT OF BANKS

5. Designation of fertility centre

The Minister may, on the recommendation of the Council, by statutory instrument, designate a health unit as a fertility centre.

6. Application for designation of fertility centre

- (1) A health unit that seeks to be designated as a fertility centre shall apply to the Council in a manner prescribed by regulations made under this Act.
- (2) The Council shall, before recommending a health unit for designation as a fertility centre to the Minister, satisfy itself that the applicant has complied with the requirements prescribed under this Act.
- (3) The Council shall consider an application for designation of a health unit as a fertility centre and make a recommendation to the Minister within thirty days from the date of receipt of the application.
- (4) Upon receipt of the recommendation of the Council under subsection (3), the Minister may within twenty-one days, issue a designation certificate to the applicant.
- (5) Where the Minister refuses to issue a designation certificate, the Minister shall inform the applicant, in writing, giving reasons for the refusal.

(6) The Minister shall, by notice in the Gazette or a newspaper of nationwide circulation, publish a list of designated fertility centres annually.

7. Suspension and revocation of designation certificate

- (1) The Minister may, on the recommendation of the Council, suspend or revoke a designation certificate where a fertility centre does not meet the requirements prescribed under this Act.
- (2) The Minister shall, in consultation with the Council, by statutory instrument, prescribe the grounds for suspension and revocation of a designation certificate.

8. Accreditation of fertility centre

A fertility centre designated under section 5 shall be accredited annually, by the Minister, on the recommendation of the Council.

9. Establishment of bank

- (1) A bank shall be established within a fertility centre.
- (2) The Minister may, on the recommendation of the Council, approve the establishment of a bank under subsection (1).
- (3) The Minister shall, in consultation with the Council, by statutory instrument, prescribe the conditions for approval of a bank.
- (4) Where the Minister is satisfied that an applicant meets the conditions prescribed under subsection (3), the Minister may issue a certificate of approval of a bank.
- (5) Where the Minister refuses to issue a certificate of approval of a bank, the Minister shall inform the applicant, in writing, giving reasons for the refusal.

10. Suspension and revocation of certificate of approval of bank

- (1) The Minister may, on the recommendation of the Council, suspend or revoke a certificate of approval of a bank.
- (2) The Minister shall, in consultation with the Council, by statutory instrument, prescribe the grounds for suspension and revocation of a certificate of approval of a bank.

PART IV—PROVISION OF HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES

11. Human assisted reproductive technology services to be provided in a fertility centre by registered medical practitioner

- (1) A person who is not a registered medical practitioner shall not provide human assisted reproductive technology services.
- (2) A registered medical practitioner shall not provide human assisted reproductive technology services to a person in a place other than a fertility centre.
- (3) A person who contravenes subsection (1) or (2) commits an offence and is liable, on conviction, to a fine not exceeding ten thousand currency points or for a term of imprisonment not exceeding ten years, or both.

12. Information on human assisted reproductive technology services

A registered medical practitioner shall, before providing human assisted reproductive technology services to a person, avail the following information to the person—

(a) human assisted reproductive technology services offered by the fertility centre and the procedures involved in obtaining the human assisted reproductive technology services;

- (b) the likely outcome of the use of human assisted reproductive technology services;
- (c) the facilities within the fertility centre for human assisted reproductive technology services;
- (d) fertility centre's policies on confidentiality and protection of personal data;
- (e) the right to withdraw or vary consent;
- (f) procedures for handling complaints by the fertility centre;
- (g) medical fees for human assisted reproductive technology services; and
- (h) any other relevant information.

13. Medical examination

- (1) A registered medical practitioner shall, before providing human assisted reproductive technology services to a person, carry out a medical examination on the person.
- (2) Where a registered medical practitioner carries out a medical examination on a person who intends to donate a gamete and the medical examination establishes that the person has a genetic disease, the registered medical practitioner shall not harvest a sperm or oocyte from the person.
- (3) The Minister shall, by statutory instrument, determine the genetic diseases referred to in subsection (2).

14. Fertility centre to maintain a register

A fertility centre shall maintain a register of all information collected by the fertility centre.

Donation and Storage of Gamete or Embryo

15. Donation of gamete or embryo

- (1) A person may donate a gamete or embryo to a fertility centre or recipient for purposes of human assisted reproductive technology.
- (2) A person shall, prior to donation, enter into an agreement for the donation of a gamete or embryo with a fertility centre or recipient.
 - (3) The agreement referred to in subsection (2) shall—
 - (a) provide for consent by a donor;
 - (b) prescribe conditions for the use of the gamete or embryo;
 - (c) specify the length of time of intended storage of gamete or embryo;
 - (d) specify the number of recipients that may use the donor's gamete or embryo;
 - (e) specify the use of a donor's gamete or embryo where a donor dies; or
 - (f) any other condition as the parties may determine.
- (4) Where a donor and recipient enter into an agreement under subsection (2), the donor and recipient shall provide the fertility centre, a copy of the agreement.

16. Information to be provided to registered medical practitioner

- (1) A registered medical practitioner shall obtain the following information from a person intending to donate a gamete or embryo—
 - (a) age of the person;

- (b) name;
- (c) ethnic origin;
- (d) nationality;
- (e) family health history;
- (f) medical history;
- (g) physical traits; and
- (h) professional qualifications and skills.
- (2) A registered medical practitioner shall—
- (a) utilise the information in subsection(1) to determine the suitability of a person to donate a gamete or embryo;
- (b) inform a person intending to obtain a child using a donated gamete or embryo of the information obtained in subsection (1).
- (3) Notwithstanding subsection (1), the Minister may, in consultation with the Council, by regulations, prescribe other information to be provided to a registered medical practitioner by a person intending to donate a gamete or embryo.

17. Age of donor

- (1) A registered medical practitioner shall not harvest a gamete from a person who is below eighteen years of age.
- (2) A person who contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding ten thousand currency points or for a term of imprisonment not exceeding ten years, or both.

18. Storage of gamete or embryo

- A fertility centre which receives or harvests a gamete or creates an embryo shall store the gamete or embryo in a bank.
- Where a fertility centre receives or harvests a gamete or creates an embryo, the fertility centre shall enter into an agreement with a donor, recipient or any other fertility centre for storage of the gamete or embryo in a bank.
- A donor, recipient or fertility centre, as the case may be, (3) shall bear the cost of storage of a gamete or embryo.
- The Council shall prescribe clinical guidelines for storage of gamete and embryo.
- (5) A fertility centre shall ensure that a gamete or embryo is stored in accordance with the clinical guidelines prescribed by the Council under subsection (4).

19. Parentage in human assisted reproductive technology

A man and woman who use-

- (a) their own gamete or embryo; or
- (b) another person's gamete or embryo, to obtain a child through human assisted reproductive technology, shall be the parent of the child.

PART V—SURROGACY

20. Surrogacy

An intending parent shall use surrogacy in accordance with this Act.

21. Conditions for intending parent

An intending parent may opt for surrogacy where a registered medical practitioner has, upon examination of the intending parent, established that—

- (a) the intending parent suffers primary or secondary infertility; or
- (b) the intending parent suffers health challenges which affect the intending parent's ability to reproduce.

22. Conditions for surrogate mother

- (1) A fertility centre or registered medical practitioner shall, before providing human assisted reproductive technology services to a surrogate mother, ascertain that the surrogate mother—
 - (a) is aged eighteen years and above; and
 - (b) has entered into a surrogacy agreement under section 23 with an intending parent.
- (2) A registered medical practitioner who contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding five hundred currency points or imprisonment not exceeding five years, or both.
- (3) A fertility centre which contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding five thousand currency points.

23. Surrogacy agreement

- (1) An intending parent who wishes to get a child through surrogacy, shall enter into a surrogacy agreement with a surrogate mother.
- (2) The surrogacy agreement in subsection (1) shall be in writing and in accordance with this Act.
- (3) Where an intending parent does not wish to be a party to the surrogacy agreement in subsection(1), the intending parent shall authorise, by agreement, a fertility centre to enter into the surrogacy agreement on behalf of the intending parent.

- (4) An intending parent shall before a registered medical practitioner provides human assisted reproductive technology services to a surrogate mother, provide a copy of an executed surrogacy agreement to a fertility centre.
- (5) A registered medical practitioner shall in providing human assisted reproductive technology services to a surrogate mother—
 - (a) ascertain that a surrogate mother understands her rights and obligations under the surrogacy agreement; and
 - (b) in as much as possible, take into account the terms and conditions of the surrogacy agreement.

24. Parentage in surrogacy

- (1) An intending parent shall be the parent of a child born through surrogacy.
- (2) For avoidance of doubt, where a surrogate mother gives birth to a child under a surrogacy agreement, the surrogate mother shall not be a parent of the child born through surrogacy.

25. Medical care for surrogate mother

An intending parent shall provide medical care for a surrogate mother during surrogacy.

26. Appointment of guardian

An intending parent shall appoint a guardian, in the surrogacy agreement, to hold parental responsibilities of his or her child born through surrogacy in the event of his or her death before the child is born.

PART VI—REGISTER OF HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY

27. Report to Council

(1) A fertility centre shall annually report to the Council on the following—

- (a) number of persons who have used human assisted reproductive technology services;
- (b) number of children born through human assisted reproductive technology;
- (c) outcome of the human assisted reproductive technology services including success and failure rates; and
- (d) any other relevant information as the Council may require.
- (2) A fertility centre which contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding five hundred currency points.
- (3) A fertility centre shall, in providing information to the Council in subsection (1), ensure compliance with the Medical and Dental Practitioners Act, Data Protection and Privacy Act, 2019 and any other relevant law.

28. Register

The Council shall maintain a register of the following information—

- (a) list of fertility centres;
- (b) nature of services provided by fertility centres; and
- (c) information provided by fertility centres under section 27.

29. Access to information in register

- (1) A person above eighteen years may, upon payment of a prescribed fee, apply to the Council, in writing, to access information contained in the Register
- (2) The Minister shall, in consultation with the Council, make regulations for access to information contained in the Register.

PART VII—OFFENCES AND PENALTIES

30. Prohibition of use of gamete without consent

- (1) A registered medical practitioner who, without consent of a person seeking human assisted reproductive technology services uses—
 - (a) his or her own gamete or embryo; or
 - (b) a gamete or embryo other than the one selected by the person,

in providing human assisted reproductive technology services to the person, commits an offence.

(2) A person who contravenes subsection (1) is liable, on conviction, to imprisonment for life.

31. Prohibition of use of genetic material not of human origin

- (1) A registered medical practitioner shall not implant a human admixed embryo or any other embryo that is not a human embryo into a woman's uterus.
- (2) A registered medical practitioner who contravenes subsection (1) commits an offence and is liable, on conviction, to imprisonment for life.
 - (3) For purposes of this section—

"human admixed embryo" means—

- (a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with—
 - (i) two human pronuclei;
 - (ii) one nucleus of a human gamete or of any other human cell; or

- (iii) one human gamete or other human cell;
- (b) any other embryo created by using—
 - (i) human gametes and animal gametes; or
 - (ii) one human pronucleus and one animal pronucleus;
- (a) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of an embryo;
- (b) a human embryo that has been altered by the introduction of one or more animal cells; or
- (c) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal ("animal DNA") but in which the animal DNA is not predominant.

32. Prohibition of advertising or arrangement of surrogacy

- (1) A person shall not advertise for surrogacy.
- (2) A person who contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding three hundred currency points or for a term of imprisonment not exceeding two years, or both.

PART VIII—MISCELLANEOUS

33. Restriction on disclosure of information

(1) A person shall not disclose information under this Act, except in accordance with the law.

(2) A person who contravenes subsection (1) commits an offence and is liable, on conviction, to a fine not exceeding one thousand currency points or for a term of imprisonment not exceeding five years, or both.

34. Regulations

The Minister shall, in consultation with the Council, by statutory instrument, make regulations for carrying out the purposes of this Act.

35. Transitional provisions

A person who, immediately before the commencement of this Act, was carrying out activities regulated under this Act, shall within two years of the commencement of this Act, comply with this Act.

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SCHEDULE

A currency point is equivalent to twenty thousand shillings.

Cross References

Data Protection and Privacy Act, 2019 Medical and Dental Practitioners Council Act Cap. 272