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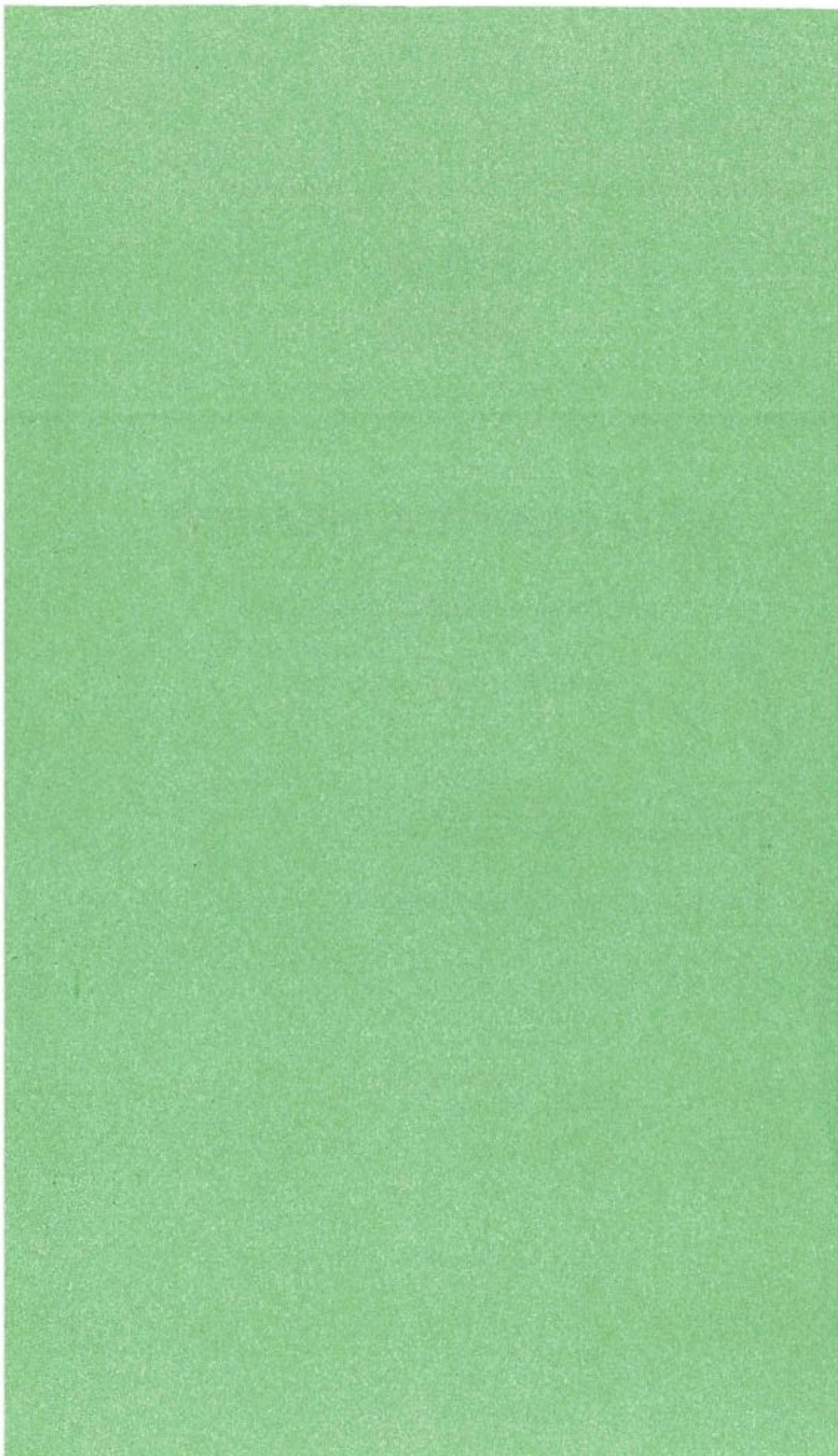
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THE ASSISTED REPRODUCTIVE TECHNOLOGY BILL, 2022

A Bill for

AN ACT of Parliament to provide for the regulation of assisted reproductive technology; to prohibit certain practices in connection with assisted reproductive technology; to establish an Assisted Reproductive Technology Directorate; to make provision in relation to children born of assisted reproductive technology processes and for connected purposes.

ENACTED by the Parliament of Kenya, as follows—

PART I—PRELIMINARY

1. This Act may be cited as the Assisted Reproductive Technology Act, 2022. Short title

2. In this Act, except where the context otherwise requires— Interpretation.

“assisted reproductive technology” means fertilization in a laboratory dish of processed sperm with processed eggs which have been obtained from an ovary, whether or not the process of fertilization is completed in the laboratory dish;”

“assisted reproductive technology expert” means an obstetrician or gynaecologist that has sub-specialized in reproductive endocrinology and fertility medicine;

“assisted reproductive technology services” includes the diagnostic and screening, endoscopic surgery, intra-uterine insemination, in-vitro fertilization, intracytoplasmic sperm injection, cryo-preservation, pre-implantation genetic screening, pre-implantation genetic diagnosis, onco-fertility, gamete and embryo donation, or surrogacy provided to infertile and sub-fertile man or woman;

“Cabinet Secretary” means the Cabinet Secretary for the time being responsible for health;

“child” means any human being under the age of eighteen years;

“commissioning parents” means a man and woman whether a couple or parties to a marriage who enter into a

surrogacy arrangement seeking assistance in procreation through the help of a surrogate mother or donor;

“couple” means a male and female who are in an association notwithstanding whether such association may be recognized as a marriage under any law in Kenya;

“court” means the High Court of Kenya;

“cryo-preservation” means the assisted reproductive technology process of cooling and storing gametes or embryos at very low temperatures to preserve their viability and includes embryo, egg or sperm freezing;

“diagnosis” means the process of testing and screening to ascertain the proper functioning of the reproductive systems and its processes at the beginning of the assisted reproductive technology process;

“Directorate” means the Assisted Reproductive Technology Directorate established under section 5;

“donation” for purposes of this Act, means a process in Assisted Reproductive Technology, of voluntarily giving gametes or embryos for purposes of procreation;

“donor” means a person who voluntarily gives his or her gametes for the purpose of fertilization in an assisted reproductive technology process and the person need not be the spouse of the person she or he is donating the gametes to;

“egg” means a live human ovum;”

“embryo” means a live pre-born person or child from fertilization or conception until transfer into the adoptive or surrogate mother;”

“embryologist” means a specialist who deals with gametes and assists in the process of fertilization in the laboratory;

“embryology” means a branch of biology that deals with gametes and development of embryos;

“endoscopic surgery” means a surgery in assisted reproductive technology involving techniques that limit the size of incisions performed with one or more small incisions instead of large incisions, and passing a telescope with a video camera through the incision into the body cavity;

“father” means a man who in the case of a child who is being carried by a woman as a result of the placing in the woman an embryo or sperm and eggs or the artificial insemination of the woman—

- (a) the man donated his sperms for the process of assisted reproduction, and at the time of placing in the woman the embryo or the sperm and eggs or artificial insemination of the woman—
 - (i) the woman was party to a marriage with the man; or
 - (ii) the woman was not party to a marriage with the man but has subsequently contracted a marriage to the man; or
 - (iii) the man and the woman have never contracted a marriage, but the man has in agreement with the mother, written a parental agreement acquiring parental rights of a father, or
- (b) the man did not donate his sperms for the process of assisted reproduction, and at the time of placing in the woman the embryo or the sperm and eggs or artificial insemination of the woman—
 - (i) the man was party to a marriage with the woman; or
 - (ii) the man has in agreement with the woman, written a parental agreement acquiring parental rights of a father;

“gamete” means a mature sperm from a man or a mature egg from a woman capable of fusing with a gamete of the opposite sex to produce an embryo;”

“infertile or sub-fertile client” means a man and woman whether a couple or parties to a marriage who are not able to procreate naturally;

“infertility” means the inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception;

“intracytoplasmic sperm injection” means an assisted reproductive technology process whereby a single healthy

sperm is injected directly into the cytoplasm of a female egg outside the body;

“in-vitro fertilization” means an assisted reproductive technology process where an egg is fertilized by a sperm in a test-tube or elsewhere outside the body;

“mother” means a woman who is carrying or has carried a child as a result of placing in her an embryo or sperms and eggs or artificial insemination of the woman under a process of assisted reproduction and shall not include a woman carrying a child under a surrogate motherhood agreement;

“oocyte” means naturally ovulating oocyte in the female genetic tract;

“parties to a marriage” means a man and a woman married to each other;

“pre-implantation genetic diagnosis” means a process in assisted reproductive technology which involves assessment of the embryo for pre-existing hereditary diseases and eliminating the same before the transfer of the embryo to a woman’s womb;

“pre-implantation screening” means a process in assisted reproductive technology to determine the number of chromosomes in a developing embryo in specific cases;

“primitive streak” means an embryo that develops in the early stages of human reproduction, that is to be taken to have appeared in any embryo not later than the end of the period of fourteen days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored and the presence of which signifies the creation of a unique human being;

“procreation” means the process of conceiving and delivering a baby, whether through an assisted reproduction technology process or through natural means;

“sperm” means the male gametes produced in the testicles and contained in semen;

“surrogacy” means a term in assisted reproductive technology, of a woman carrying and giving birth to a baby for a commissioning parent or couple;

“surrogate mother” means a woman who has agreed to carry a pregnancy to term for another woman under a surrogacy agreement and lays no legal claim to the born child;

“treatment services” for purposes of this Act, means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to get pregnant and to carry the pregnancies to term.

3. This Act applies to all processes of facilitated human fertilization undertaken outside the human body, whether or not the process is completed outside the human body.

Application.

4. The object and purpose of this Act is to—

Object and purpose of the Act.

- (a) provide a framework for the protection and advancement of assisted reproductive technology services for every person;
- (b) create an enabling environment for the reduction of infertility and sub-fertility in Kenya; and
- (c) ensure access to quality and comprehensive assisted reproductive technology services in line with Article 43(1)(a) of the Constitution.

PART II—THE ASSISTED REPRODUCTIVE TECHNOLOGY DIRECTORATE

5. Subject to section 18 of the Health Act, 2017 the Cabinet Secretary shall form a directorate to be known as the Assisted Reproductive Technology Directorate.

Assisted Reproductive Technology Directorate, No. 21 of 2017, Functions of the Directorate.

6. The functions of the Directorate shall be to—

- (a) develop standards, regulations and guidelines on assisted reproductive technology;
- (b) advise the Cabinet Secretary on matters relating to the treatment and care of persons undergoing assisted reproductive technology and to advise on the relative priorities to be given to the implementation of specific measures in regard to assisted reproductive technology;
- (c) promote research on the conduct, control and treatment of assisted reproductive technology;

- (d) develop programs for awareness creation on the methods of assisted reproductive technology treatment;
- (e) prescribe minimum requirements for the physical infrastructure for assisted reproductive technology clinics;
- (f) prescribe, in consultation with the relevant government agency, the minimum educational requirements for assisted reproductive technology experts and embryologists;
- (g) in consultation with the relevant government agency, inspect and accredit the facilities for the training of experts and embryologists to ensure compliance with set standards;
- (h) maintain and make available to the public a register of information on all the licenced assisted reproductive technology facilities in Kenya;
- (i) in consultation with the Medical Practitioners and Dentist Council, maintain and make available to the public a register of information on all the licenced assisted reproductive technology experts and embryologists;
- (j) grant, vary, suspend and revoke licenses;
- (k) keep under review information about embryos and any subsequent development of embryos;
- (l) provide advice and information to persons receiving assisted reproductive technology treatment including persons providing gametes or embryos under this Act;
- (m) disseminate information to the public on reproductive health that may relate or affect assisted reproductive technology;
- (n) establish and maintain a confidential national database on persons receiving assisted reproductive technology treatment services or providing gametes or embryos for use; and

- (o) perform such other functions as may be necessary for the better carrying out of the functions of the Directorate under this Act.

7. The National Government shall—

Obligations of the
National
Government.

- (a) put in place the necessary mechanisms and infrastructure to ensure access to the highest attainable standard and quality of cost-effective assisted reproductive technology services;
- (b) provide adequate resources necessary to ensure access to the highest attainable standard and quality of cost-effective assisted reproductive technology services;
- (c) provide regulations to ensure assisted reproduction health services are covered by every health insurance provider including the National Health Insurance Fund; and
- (d) collaborate with the county governments in expanding and strengthening the access and delivery of assisted reproductive health services in counties.

8. Each County Governments shall—

Obligations of
County
Governments.

- (a) collaborate with the National Government in expanding and strengthening the access and delivery of assisted reproductive health services in the respective counties;
- (b) allocate in the county budget, the funds necessary for the provision of quality, cost-effective assisted reproductive technology services in the county health systems, including finances required to hire adequate personnel;
- (c) procure sufficient equipment, medicine, medical supplies required to adequately cater for assisted reproductive health care services in the respective counties;
- (d) carry out sensitization programmes related to assisted reproductive technology; and
- (e) establish linkages and networks with local and international development partners to mobilise

and source for funding to promote the delivery of quality and cost-effective assisted reproductive technology services in the county.

9. (1) The Directorate shall consist of—

Composition of
the Directorate.

(a) a Director; and

(b) such other staff as the Cabinet Secretary may, in consultation with the Director, consider necessary for the performance of the functions of the directorate under this Act.

(2) The Director and staff of the Directorate shall be competitively recruited and appointed on such terms and conditions as the Cabinet Secretary shall, in consultation with the Salaries and Remuneration Commission, determine.

10. The Directorate may engage experts or consultants as it considers appropriate, for the discharge of the functions of the Directorate.

Experts and
consultants.

PART III — PROHIBITED ACTIVITIES

11. A person shall not create, keep or use an embryo at any stage of development, either from fertilization or conception until a transfer to a woman except as provided under this Act.

Use of embryo.

12. (1) No person shall make use of any human reproductive material for the purpose of creating an embryo unless the donor of the material has given written consent, in accordance with the prescribed Regulations, to its use for that purpose.

Consent of
parties.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

13. (1) No person shall remove a human reproductive material from the body of a donor after the death of the donor for the purpose of assisted reproductive technology unless the donor of the material had given written consent, in a manner prescribed by Regulations, to its removal for that purpose.

Posthumous use
without consent.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

14. A person qualifies to undertake assisted reproductive technology, where it is certified by a medical doctor that the person requires assisted reproductive technology on medical or health grounds.

Circumstances for undertaking assisted reproductive technology.

15. (1) A person shall not undertake assisted reproductive technology for—

Circumstances under which assisted reproductive technology is precluded.

- (a) any purpose other than human procreation;
- (b) experimental purposes aimed at modifying the human race; or
- (c) purely speculative and commercial purposes.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

16. (1) A person shall not for purposes of assisted reproductive technology place in a woman —

Use of embryo in a woman.

- (a) an embryo other than a human embryo; or
- (b) a gamete other than a human gamete.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

17. (1) No person shall obtain a sperm or ovum from a donor under eighteen years of age, or use any sperm or ovum obtained from a donor under eighteen years of age except for the future human procreation by the minor and with the consent of the parent or legal guardian of the minor.

Gametes obtained from minor.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to

imprisonment for a term not exceeding five years, or to both.

18. (1) The Directorate shall not issue a license that allows— Directorate not to issue license.

- (a) the keeping or using of an embryo other than a human embryo;
- (b) the keeping or using of an embryo after the appearance of the primitive streak after five days;
- (c) the placing of an embryo in any animal;
- (d) the keeping or using of an embryo in circumstances prohibited under this Act or as prescribed by Regulations;
- (e) the replacing of any part of an embryo with another part from a cell of any person or embryo or any subsequent development of an embryo except where such replacement is meant to solve medical problems; or
- (f) any form of human cloning.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

19. (1) A person shall not— Use of gametes.

- (a) store or use any gametes save as provided under this Act;
- (b) in the course of providing assisted reproductive technology treatment services to a woman, use the sperm of any man without his consent;
- (c) in the course of providing assisted reproductive treatment services for a woman, use the egg of another woman without her consent;
- (d) mix human gametes with the live gametes of an animal; or
- (e) place sperms and eggs or embryo in a woman except in pursuance of a license as provided for under this Act.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

PART IV—RIGHTS OF PARENTS, DONORS AND CHILDREN

20. Where the sperm of a man, or any embryo the creation of which was brought about with the sperm of the man was used after the death of the man, the man shall not be treated as the father of the child unless—

Use of sperm after the death of a man.

- (a) the mother was married to the man at the time of the death of the man; and
- (b) the man had consented to parentage.

21. (1) Every person has the right to access the highest standard and quality of attainable and cost-effective assisted technology reproductive technology services.

Right to assisted reproductive technology.

(2) Assisted reproductive technology services shall be provided by qualified experts licensed by the Directorate.

(3) An assisted reproductive technology expert shall, before providing assisted reproductive technology service—

- (a) provide information necessary to assist in the making of an informed decision to all parties concerned, and in particular, information concerning—
 - (i) the various assisted reproductive technology methods available;
 - (ii) the chances of success for various assisted reproductive technology methods;
 - (iii) the advantages, disadvantages and risks of the various assisted reproductive technology methods; and
 - (iv) the cost of treatment for different assisted reproductive technology methods;
- (b) advise the parties on the need for professional counselling and have them undergo the same on the implications of the various methods; and

- (c) ensure promotion and preservation of the health, safety and dignity of the parties seeking assisted reproductive technology services.

22. The national and county governments shall put in place measures to ensure that all intersex persons have access to assisted reproductive technology services.

Right to assisted reproductive technology by intersex persons.

23. (1) An assisted reproductive technology expert shall obtain prior informed and written consent from the parties before providing any assisted reproductive technology service under the Act or any other law.

Consent to assisted reproductive technology service.

(2) The consent referred to in subsection (1) shall make express provisions on what should be done with the gametes in case of—

- (a) the death of any of the parties seeking assisted reproductive technology services; and
- (b) incapacity of any of the parties seeking assisted reproductive technology services.

(3) The assisted reproductive technology clinics and assisted reproductive technology banks shall not cryo preserve any human embryos and or gamete without specific instructions and consent in writing from all the parties seeking assisted reproductive technology in respect of what should be done with the gametes or embryos in case of death or incapacity of any of the parties.

(4) The consent of any of the parties obtained under this section may be withdrawn at any time prior to the process of implanting the embryos or the gametes in the woman's uterus.

24. (1) An assisted reproductive technology expert shall ensure—

Duties of assisted reproductive technology expert.

- (a) confidentiality is maintained throughout the entire process of provision of assisted reproductive technology services;
- (b) the donor has been screened for all diseases and conditions that may endanger the health of the parents, the surrogate or the child; and
- (c) all parties are aware and understand the rights of the child born through the assisted reproductive technology process.

(2) An assisted reproductive technology expert, shall, before receiving gamete or embryo donation, collect the following information from the donor—

- (a) a passport size photo;
- (b) physical characteristics;
- (c) ethnic origin;
- (d) family history;
- (e) medical history;
- (f) interests and hobbies; and
- (g) professional qualifications and skills.

(3) The information obtained under subsection (2) shall be held by the licensed facility, and shall not be disclosed in any way that may identify the receiver and donor.

25. The parties to a marriage under section 2—

Parties to a marriage.

- (a) are parties to a marriage recognized under any of the systems of laws in Kenya, and subsisting at that time;
- (b) include parties to a void marriage if either or both of the parties reasonably believed at that time that the marriage was valid; or
- (c) applies whether the woman was in Kenya or elsewhere at the time of the assisted reproductive process.

26. (1) A child born out of assisted reproductive technology under this Act shall have the same legal rights under the Constitution or any other written law as that of a child born through sexual intercourse.

Rights to accrue to child.

(2) The health and well-being of children born through the application of assisted human reproductive technologies shall be given priority in all decisions respecting their use.

(3) Where a married couple obtains a divorce after the creation of an embryo, both partners reserve the right to withdraw consent of the implantation of the embryo which has been created by their sperm or ovum.

(4) Where a sperm or ovum is donated from a man or woman of a different nationality, the child shall adopt the nationality of the intended parents.

(5) Where a surrogate who is not a Kenyan citizen gives birth to a child, the child shall adopt the nationality of the intended parents.

27. (1) A woman of twenty-five years or more, who has given birth at least to one child and who understands the rights and obligations accruing under a surrogacy agreement, may, at the request of a couple, consent to a process of assisted reproduction for purposes of surrogate motherhood.

Surrogate
motherhood.

(2) The surrogate mother under subsection (1) shall carry the child on behalf of the parties to a marriage or couple and shall relinquish all parental rights at birth over the child.

28. (1) Parties to a marriage or commissioning parents intending to enter into a surrogacy agreement with any woman shall sign a surrogacy agreement in a prescribed form before the process is undertaken.

Surrogacy
agreements.

(2) A person may enter into a surrogacy agreement under subsection (1) only if—

- (a) the person has the capacity to enter into the agreement under this Act and any other relevant written law in Kenya; and
- (b) understands the rights and obligations that may arise or accrue under this Act and the agreement.

(3) A surrogacy agreement under subsection (1) is valid only—

- (a) if the agreement is in writing and signed by all the parties;
- (b) if the agreement is entered into within the Republic of Kenya;
- (c) if the agreement includes provisions for the contact, care, upbringing and general welfare of the child that is born, including the position of the child in the event of—
 - (i) death of the commissioning parent, or if a couple or parties to a marriage, death of one

of the commissioning parents before the birth of the child; or

- (ii) separation or divorce of the commissioning parents who were a couple or parties to a marriage, before the birth of the child;
- (d) where the commissioning parent or commissioning parents agree to meet the prenatal regiment and birth expenses of the surrogate mother;
- (e) where signatures to the surrogacy agreement are witnessed by a minimum two witness from each of the parties to the agreement;
- (f) where there are separate and independent advocates of the High Court of Kenya representing the parties to the agreement; and
- (g) where legal fees are paid by the commissioning parent, commissioning parents or parties to marriage.

(4) The form shall indicate the names of the parents of the child to be born through assisted reproductive process.

(5) The entry in the form shall be conclusive proof of parentage of the child and shall be used for purposes of registration of birth and any other legal processes.

(6) Where there is a dispute as to the parentage of a child born out of assisted reproductive process, the aggrieved party may apply to Court within sixty days of the birth of the child for determination of the parentage of the child.

(7) The parties to a marriage shall not give any monetary or other benefits to the surrogate mother other than for expenses reasonably incurred in the process of surrogacy.

29. (1) A surrogacy agreement may be terminated—

Termination of
surrogacy
agreement.

- (a) automatically, following the termination of pregnancy in accordance with this Act or any other written law;
- (b) before the implantation of a fertilized embryo in the surrogate mother's womb; or

- (c) where a dispute arises between commissioning parents, and before the fertilized embryo is implanted in the surrogate mother.

(2) Parties shall not terminate the agreement after the transfer of the embryo or embryos into the womb of the surrogate mother.

30. (1) The Commissioning parent or parents, under the surrogacy agreement shall be the legal parent or parents of the child and not discriminate against the child.

Obligations under
surrogacy
agreement.

(2) In the event of multiple pregnancies arising out of a surrogacy agreement, all the children born out of the pregnancy shall be the children of the commissioning parent or commissioning parents and the rights and obligations for all parties shall vest as if the pregnancy had borne only one child.

(3) Where a child is born out of a surrogacy arrangement—

- (a) the commissioning parent or commissioning parents shall be listed as the parents both in the birth notification and in the birth certificate; and
- (b) the child shall acquire the citizenship of the commissioning parent or commissioning parents under Article 14(1) of the Constitution of Kenya.

(4) Notwithstanding the provisions of section 28(7) the surrogate mother may claim from the commissioning parent or commissioning parents the following—

- (a) compensation directly relating to the process of in-vitro fertilization, pregnancy, ante-natal, birth, post-natal care and post-delivery complications;
- (b) loss of earnings by the surrogate mother as a result of the surrogacy; and
- (c) insurance to cover the surrogate mother for any acts that may lead to death or disability of the surrogate mother as a result of the surrogacy.

Cap. 160.

(5) The surrogate mother shall—

- (a) not terminate the pregnancy except under the provisions of the law;

- (b) hand over the child to the commissioning parent or commissioning parents immediately upon the birth of the child;
- (c) have no rights or obligation regarding the child; and
- (d) not contact the child, whether directly or by use of proxy, unless provided for in the agreement.

(6) A child born as a result of a surrogacy agreement shall not be considered a dependant of the surrogate under the Law of Succession Act.

(7) A person shall not accept consideration for arranging for the services of a surrogate mother, make such an arrangement for consideration or advertise the arranging of such services.

31. A person shall not do any act, at any stage of an assisted reproductive process, to determine the sex of the child to be born through the process of assisted reproductive technology.

Prohibition of sex selection.

32. (1) 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.

Restriction on sale of human gametes, zygotes and embryos and prohibition of commercial artificial reproductive technology.

(2) A person shall not sell, transfer or use gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party within and outside Kenya.

PART V—ACCESS TO INFORMATION

33. The Directorate shall keep and maintain a register containing particulars on—

Assisted reproductive technology register.

- (a) the assisted reproductive treatment services provided to persons;
- (b) the keeping or use of gametes of persons or of an embryo taken from any particular woman, or
- (c) persons who undergo assisted reproduction process;

- (d) donors of embryos and gametes; and
- (e) persons conceived in consequence of assisted reproduction treatment services.

34. (1) A person who has attained the age of twenty-one may by notice to the Directorate require the Directorate to—

Provision of information by the Directorate.

- (a) avail information on whether the applicant was conceived by means of assisted reproduction; and
- (b) state whether or not the information contained in the register shows that the applicant, and a person specified in the request as a person whom the applicant proposes to marry would or might be relatives.

(2) The Directorate shall comply with the request of the applicant made under subsection (1) if—

- (a) the information contained in the register shows that the person was, or may have been, born in consequence of assisted reproduction treatment services, and
- (b) the person has been given an opportunity to receive counseling in regard to the implications of compliance with the request.

(3) The Directorate shall not give information regarding the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a license applied was provided with the information at a time when the Directorate was not required to give the information.

35. (1) The Directorate shall not avail information to a person below the age of eighteen years unless the information is necessary for a medical procedure relating to the minor.

Minor not to be given information.

(2) Where a minor seeks such information, the minor may, through a legal guardian, give notice to the Directorate requesting the Directorate to give the information and the Directorate shall give the information, if—

- (a) the information contained in the register shows that the minor was, or may have been, born in

consequence of assisted reproduction process, and

- (b) the minor has been given an opportunity to receive counseling on the implications of compliance with the request.

36. (1) Where a government agency makes a claim to the Directorate seeking to verify whether a man is or is not the father of a child and the Directorate shall comply with the request made by the government agency unless it appears to the Directorate that there is not sufficient reason to seek for that information.

Information from the Directorate.

(2) Where the government agency is aggrieved by the decision of the Directorate, the agency may appeal to the Court for determination of the matter.

37. (1) A person who is or has been a member or employee of the Directorate shall not disclose any information which the person holds or has held as a member or employee of the Directorate.

Restriction on disclosure of information.

(2) The information specified under subsection (1) is—

- (a) information contained in the register kept pursuant to section 33 of this Act; and
- (b) any other information obtained by any member or employee of the Directorate on terms or circumstances requiring it to be held in confidence.

(3) Subsection (1) does not apply to disclosure of information specified under subsection (2) (a) made—

- (a) to a person as a member or employee of the Directorate;
- (b) to a person to whom a license applies for the purposes of the functions under this Act;
- (c) with the consent of a person or persons whose confidence would otherwise be protected;
- (d) in pursuance of an order of a court under this Act;
- (e) to any government agency in pursuance of a

request under section 34 of this Act.

(4) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

PART VI—LICENSING

38. The Directorate in consultation with the Medical Practitioners and Dentists Council shall, in accordance with this Act issue, vary, revoke or renew a licence in relation to activities under this Act.

Licence.

39. (1) No person shall carry out assisted reproduction unless the person is issued with a valid licence under this Act.

Requirement for licence.

(2) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

40. (1) An application for a licence under this section shall be made to the Directorate in duplicate, signed by the applicant, specifying his name and place of business.

Application for licence.

(2) Every application under this section shall be accompanied by the prescribed fee.

(3) Where an application is made by a person in accordance with this section, the Directorate shall issue the person a license to carry out assisted reproduction, if satisfied that the person meets such other requirement as may be prescribed, and if not satisfied, shall refuse the application.

41. (1) The Directorate shall, before considering an application authorizing a person to undertake assisted reproductive technology on premises, arrange for the premises where assisted reproduction process is to be carried on to be inspected, and a report made regarding the inspection.

Inspection of premises before license is issued.

(2) Subject to subsection (1), the Directorate shall inspect at least once in each calendar year, any premises where assisted reproduction process is to be carried and a

report made on the inspection.

42. (1) The Directorate may, in accordance with this Act, attach conditions to a license.

General
conditions for
licenses.

(2) The conditions specified under subsection (1) are that—

- (a) the activities authorized by the license shall be carried on only on the premises to which the license relates and under the supervision of the person responsible;
- (b) any member or employee of the Directorate, shall upon identification be permitted, at all reasonable times to enter premises to which the license relates and inspect the premises including the inspection of any equipment, records and observing any activity;
- (c) proper records shall be maintained in such form as the Directorate may direct;
- (d) no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorized by the Directorate;
- (e) where gametes or embryos are supplied to a person to whom another license applies, the person shall be provided with information as may be specified by the Directorate; and
- (f) the Directorate shall be provided with copies or extracts from the records or information, in such form and at such intervals as it may specify.

(3) Every licensee shall keep and provide information to the Directorate and any government bodies on—

- (a) the persons to whom assisted reproductive technology services are provided;
- (b) the number of persons seeking assisted reproductive technology services, segregated by type of service sought, gender and outcome;
- (c) the kind of assisted reproductive technology services provided;
- (d) the persons whose gametes are kept or used for the purposes of assisted reproductive technology

services;

- (e) the persons whose gametes have been used in bringing about human procreation; and
- (f) such other matters as the Directorate may specify.

(4) No information shall be removed from any records maintained in pursuance of a license before the expiry of a period specified by the Directorate.

(5) A woman shall not be provided with any treatment services that involve—

- (a) the use of any gametes of any person, if the consent of the person is required under this Act and the consent has not been obtained;
- (b) the use of any embryo taken from another woman, if the consent of the woman from whom it was taken has not been obtained;
- (c) the procedures specified under paragraph (a) and (b), unless the woman has been provided with relevant information and given an opportunity to receive counseling on the implications of taking the proposed steps.

(6) A person who contravenes the provisions of this section commits an offence and shall, upon conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

43. (1) Every license authorizing the storage of gametes or embryos shall have the condition that—

Conditions for storage of gametes.

- (a) the gametes of a person or the resultant embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a license applies;
- (b) an embryo the creation of which has been brought about by assisted reproductive technology than in pursuance of the license shall be placed in storage only if acquired from a person to whom the license applies;

- (c) gametes or embryos which are stored shall not be supplied to a person other than in the course of providing treatment services unless that person is a person to whom a license applies;
- (d) an embryo which is created but is not transferred to the surrogate or adoptive mother for any reason shall be stored and shall be given priority in the succeeding application for assisted reproductive technology;
- (e) no gametes or embryos shall be kept in storage for longer than the statutory storage period, and
- (f) information regarding persons whose consent is required under this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Directorate may specify shall be included in the records maintained in pursuance of the license.

(2) The storage period in respect of embryos shall be a period not exceeding ten years or as the license may specify.

44. (1) Where an application for a license is made to the Directorate, the Directorate shall issue the person a license if satisfied that—

Grant of License.

- (a) the application is for a license designating the applicant as the person under whose supervision the activities to be authorized by the license are to be carried on;
- (b) either the person is the applicant or—
 - (i) the application is made with the consent of the person; and
 - (ii) the applicant is a suitable person to hold a license.
- (c) the character, qualifications and experience of the person making the application are such as are required for the supervision of the activities under this Act and that the person is qualified to discharge the duties under this Act;
- (d) the premises in respect of which the licence is to be granted are suitable for the activities, and

(e) all other requirements under this Act in relation to granting of a licence are satisfied.

(2) The Directorate may grant a licence to any person by way of renewal whether on the same or different terms.

(3) Where the Directorate is of the opinion that the information provided in the application is insufficient to enable it to determine the application, the Directorate shall not consider the application until the applicant has provided further information as the Directorate may require.

(4) The Directorate shall not grant a license unless a copy of the conditions to be imposed by the licence have been provided to, and acknowledged in writing by the applicant and the person under whose supervision the activities are to be carried on.

(5) The fee specified under section 40(2) means a fee of such amount as may be fixed from time to time by the Directorate with the approval of the Cabinet Secretary.

(6) In determining the amount of fee under subsection (5), the Directorate may have regard to the costs of performing all its functions.

(7) The Directorate may fix different fees for different circumstances and any fees paid under this section shall not be refundable.

45. (1) It shall be the responsibility of the person under whose supervision the activities authorized by a licence are carried on to ensure—

Responsibility of the supervisor.

(a) that the persons to whom the licence applies are of such character, and are qualified by training and experience, to be suitable persons to participate in the activities authorized by the licence;

(b) that proper equipment is used;

(c) that proper keeping of gametes and embryos and for the disposal of gamete or embryos that have been allowed to perish; and

(d) that the conditions of the licence are complied with.

(2) The persons to whom a licence applies under this Act are—

- (a) persons under whose supervision the activities authorized by a licence are carried on
- (b) any person designated in the licence, or in a notice given to the Directorate by the person who holds the licence or the person responsible, as a person to whom the licence applies, and
- (c) any person acting under the direction of the person responsible or of any person designated.

46. (1) The Directorate may revoke a license if satisfied—

Revocation of
licence.

- (a) that the information given for the purposes of the application for the grant of the licence was false or misleading;
- (b) that the premises to which the licence relates are no longer suitable for the activities authorized by the licence;
- (c) that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under this Act or has failed to comply with directions given in connection with any licence;
- (d) that there has been a change of circumstances since the licence was granted;
- (e) that the character of the person responsible is not as is required for the supervision of the activities or that the nominal licensee is not a suitable person to hold a licence; or
- (f) the person responsible dies or is convicted of an offence under this Act.

(2) Where the Directorate has power to revoke a license under subsection (1), the Directorate may vary any terms of the licence.

(3) The Directorate may, on application by the person responsible or the nominal licensee, vary or revoke the licence.

(4) The Directorate may, on an application by the nominal licensee, vary the licence so as to designate another person in place of the person under whom

supervision is authorized by a licence, if the Directorate is satisfied that the character, qualifications and experience of the other person are such as are required for the supervision of the activities authorized by the licence and that the person shall discharge the duties under this Act, and the application is made with the consent of the other person.

(5) Except on an application under subsection (4), the Directorate may vary a licence under this section –

- (a) if it relates to the activities authorized by the licence, the manner in which they are conducted or the conditions of the licence, or
- (b) so as to extend or restrict the premises to which the licence relates.

(6) The Cabinet Secretary shall make Regulations for the refusal, variation and revocation of licenses by the Directorate under this Act.

47. (1) Where the Directorate refuses to issue a licence or refuses to vary a licence—

Application to the
Cabinet Secretary
for review.

- (a) the applicant may apply for review to the Cabinet secretary within thirty days of the date on which the decision was communicated to the applicant; and
- (b) the Cabinet Secretary may make such determination on the review as they deem fit.

(2) The Cabinet Secretary shall give notice of its decision to the appellant and, if it is a decision to refuse a licence or to refuse to vary a licence so as to designate another person in place of the person under whom supervision is authorized by a licence, or a decision to vary or revoke a licence, shall include in the notice the reasons for the decision.

48. Where the Cabinet Secretary, upon an application for review under section 47 of this Act determines—

Appeal to the
High Court.

- (a) to refuse a licence or refuse to vary a licence so as to designate another individual in place of the person under whom supervision is authorized by a licence; or
- (b) to vary or revoke a licence,

the person on whom notice of the determination was served may appeal to the High Court.

49. (1) Where the Directorate—

- (a) has reasonable grounds to suspect that there are grounds for revoking the licence for non-compliance with this Act, and
- (b) is of the opinion that the licence should immediately be suspended,

Temporary suspension of a licence.

the Directorate may by notice suspend the licence for a period not exceeding three months.

(2) The Directorate shall give notice under subsection (1) to the person under whom supervision is authorized by a licence or, where the person under whom supervision is authorized by a licence is dead or appears to the Directorate to be unable because of incapacity to discharge the duty imposed on him under this Act, to some other person to whom the licence applies or the nominal licensee and the Directorate may, by a further notice to that person, renew the notice under subsection (1) specified in the renewal notice.

PART VIII—MISCELLANEOUS PROVISIONS

50. (1) A person commits an offence under this Act where the person knowingly or recklessly—

Offences.

- (a) contravenes any of the provisions of the Act;
- (b) contravenes any of the provisions of a notice issued under this Act; or
- (c) obstructs a person in the execution of the person's duty under the Act.

(2) Where an offence against this section is committed by a body corporate, the body corporate shall be liable to a fine not exceeding five million shillings.

51. Any person convicted of an offence under this Act for which no penalty is provided shall be liable to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

General penalty.

PART IX—PROVISIONS ON DELEGATED POWERS

52. The Cabinet Secretary, in consultation with the Directorate, may make regulations generally for the better carrying out of the provisions of this Act, and without prejudice to the generality of the foregoing, may make regulations—

Regulations.

- (a) for the eligibility of donors;
- (b) for the storage of gametes and embryos;
- (c) for the number of embryos that can be planted in a woman;
- (d) for settling disputes arising out of assisted reproduction;
- (e) for the maintenance for records;
- (f) regarding rights and duties of patients, donors surrogates and children;
- (g) in respect of the giving of consent for the use of human reproductive material or an embryo from assisted reproductive process or for the removal of human reproductive material;
- (h) in respect of the number of children that may be created from the gametes of one donor through the application of assisted reproduction procedures;
- (i) in respect of the terms and conditions of licenses;
- (j) in respect of the qualifications for licenses.
- (k) in respect of the issuance, amendment, renewal, in respect of suspension, restoration and revocation of licenses;
- (l) in respect of the information to be provided in respect of applications for a license or for the renewal or amendment of a license;
- (m) in respect of the identification and labeling of human reproductive materials and embryos from assisted reproductive process used in treatment services;
- (n) in respect of the collection, use and disclosure of information regarding assisted reproduction processes;
- (o) in respect of counseling services; or

- (p) in respect of research relating to assisted reproductive technology treatment, services and products.

MEMORANDUM OF OBJECTS AND REASONS

The principal object of the Bill is to provide for the regulation of assisted reproductive technology; to prohibit certain practices in connection with assisted reproductive technology; to establish an Assisted Reproductive Technology Directorate; to make provision in relation to children born of assisted reproductive technology processes and matters connected thereto.

PART I (Clause 1-4) of the Bill contains the preliminary provisions.

PART II (Clause 5-10) of the Bill provides for of the Assisted Reproductive Technology Directorate including: the functions of the Directorate; the obligations of the National Government; the obligations of County Governments; the composition of the Directorate; and experts and consultants.

PART III (Clause 11-19) of the Bill provides for matters regulating prohibited activities including; the use of embryos; consent of parties; posthumous use without consent; circumstances for undertaking assisted reproductive technology; circumstances under which assisted reproductive technology is precluded; use of embryo in a woman; gametes obtained from minor; and use of gametes.

PART IV (Clause 20-32) of the Bill provides for matters regulating rights of parents donors, and children including: use of sperm after the death of a man; right to assisted reproductive technology; right to assisted reproductive technology by intersex persons; consent to assisted reproductive technology service; duties of assisted reproductive technology expert; parties to a marriage; rights to accrue to child; surrogate motherhood; surrogacy agreements; termination of surrogacy agreements; obligations under surrogacy agreement; prohibition of sex selection; and, restriction on sale of human gametes, zygotes and embryos and prohibition of commercial artificial reproductive technology.

PART V (Clause 33-37) of the Bill provides for matters regulating access to information including: assisted reproductive technology register; provision of information by the Directorate; minor not to be given information; information from the Directorate; and restriction on disclosure of information.

PART VI (Clause 38-49) of the Bill provides for matters regulating licensing including: requirements for a licence; application for a licence; inspection of premises before license is issued; general conditions for license; conditions for storage of gametes; grant of a licence; responsibility of the supervisor; revocation of a licence; application to the

Cabinet Secretary for review; appeal to the High Court; and, temporary suspension of a licence.

PART VIII (Clause 50 & 51) of the Bill provides for matters relating miscellaneous provisions including offences and general penalty.

PART IX (Clause 52) of the Bill provides for matters on Regulations.

Statement on the delegation of legislative powers and limitation of fundamental rights and freedoms

The Bill delegates legislative powers to the Cabinet Secretary responsible for Health to make regulations for the better carrying out of the provisions of its provisions. It does not contain any provisions limiting any fundamental rights or freedom.

Statement of how the Bill concerns county governments

The Bill affects the functions of county governments as set out in the Fourth Schedule to the Constitution and is therefore a Bill concerning county governments.

Statement as to whether the Bill is a money Bill within the meaning of Article 114 of the Constitution

The enactment of this Bill shall occasion additional expenditure of public funds.

Dated the 24th November, 2022.

MILLIE ODHIAMBO MABONA,
Member of Parliament.