

SPECIAL ISSUE

Kenya Gazette Supplement No. 57 (National Assembly Bills No. 34)



REPUBLIC OF KENYA

KENYA GAZETTE SUPPLEMENT

NATIONAL ASSEMBLY BILLS, 2019

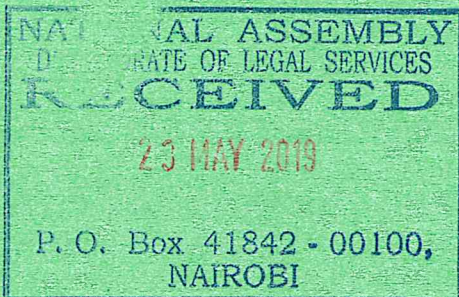
NAIROBI, 15th April, 2019

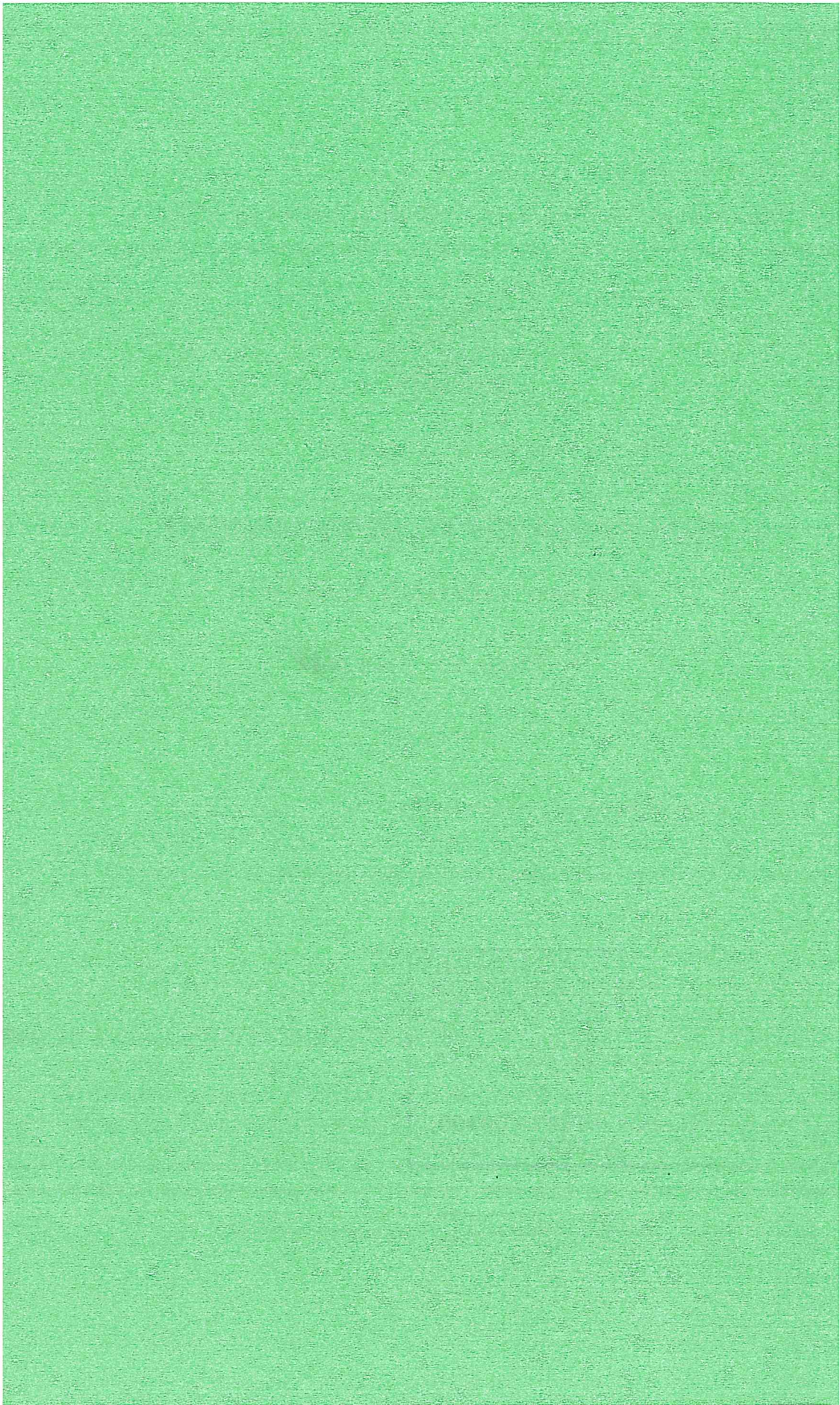
CONTENT

Bill for Introduction into the National Assembly—

PAGE

The Assisted Reproductive Technology Bill, 2019.....433





**THE ASSISTED REPRODUCTIVE TECHNOLOGY
BILL, 2019**

ARRANGEMENT OF CLAUSES

Clause

PART I—PRELIMINARY

- 1—Short title and commencement.
- 2—Interpretation.
- 3—Application.

**PART II —THE ASSISTED REPRODUCTIVE
TECHNOLOGY AUTHORITY**

- 4—Establishment of Authority.
- 5—Functions of the Authority.
- 6—Powers of the Authority.
- 7—Board of the Authority.
- 8—Term of office of members of the Authority.
- 9—Conduct of business and affairs of the Authority.
- 10—Functions of the Board.
- 11—Director of the Authority.
- 12—Staff of the Authority.
- 13—Experts and consultants.
- 14—Remuneration of Board members and staff of the Authority.
- 15—Delegation by the Authority.
- 16—Protection from personal liability.
- 17—The Seal.

PART III—PROHIBITED ACTIVITIES

- 18—Use of embryo.
- 19—Consent of parties.
- 20—Posthumous use without consent.

- 21—Assisted reproductive technology for procreation purposes.
- 22—Circumstances for undertaking assisted reproductive technology.
- 23—Circumstances under which assisted reproductive technology is precluded.
- 24—Use of embryo in a woman.
- 25—Gametes obtained from minor.
- 26—Authority not to issue license
- 27—Use of gametes.

PART IV—RIGHTS OF PARENTS DONORS, AND CHILDREN

- 28—Use of sperm after the death of a man.
- 29—Parties to a marriage.
- 30—Rights to accrue to child.
- 31—Surrogate motherhood.
- 32—Surrogacy agreements.

PART V—ACCESS TO INFORMATION

- 33—Assisted reproductive technology register.
- 34—Provision of information by the Authority.
- 35—Minor not to be given information.
- 36—Information from the Authority.
- 37—Restriction on disclosure of information.

PART VI—LICENSING

- 38—Licence.
- 39—Requirement for licence.
- 40—Application for licence.
- 41—Inspection of premises before license is issued.
- 42—General conditions for licenses.
- 43—Conditions for storage of gametes.
- 44—Grant of licence.

- 45—Responsibility of the supervisor.
- 46—Revocation of licence.
- 47—Appeal to the Authority.
- 48—Appeal to the High Court.
- 49—Temporary suspension of a licence.

PART VII—FINANCIAL PROVISIONS

- 50—Funds of the Authority.
- 51—Financial year.
- 52—Annual estimates.
- 53—Accounts and audit.
- 54—Investments of funds.
- 55—Annual reports.
- 56—Special Reports.

PART VIII—MISCELLANEOUS PROVISIONS

- 57—Offences.
- 58—General penalty.

**PART IX—PROVISIONS ON DELEGATED
POWERS**

- 59—Regulations.

**SCHEDULE—PROVISIONS AS TO THE CONDUCT
OF BUSINESS AND AFFAIRS OF THE
BOARD**

**THE ASSISTED REPRODUCTIVE TECHNOLOGY
BILL, 2019**

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 Authority; 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, 2019.

Short title

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

Interpretation.

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

“Authority” means the Assisted Reproductive Technology Authority established under section 4;

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

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

“couple” means a male and female who are in an association that may be recognised as a marriage under any law in Kenya;”

“court” means the High Court of Kenya;

“Director” means a person appointed as such under section 5;

“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;

“eggs” means live human eggs but do not include eggs in the process of fertilization;

“embryo” means a live human egg where fertilization is either in the process or complete;

“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—

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—

- (a) the woman was party to a marriage with the man; or
- (b) the woman was not party to a marriage with the man but has subsequently contracted a a marriage to the man; or
- (c) 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
- (d) 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; and
 - (ii) the man has in agreement with the woman, written a parental agreement acquiring parental rights of a father;

“gametes” means a mature sperm or egg capable of fusing with a gamete of the opposite sex to produce the fertilized egg

but does not include gametes in the process of fertilization;

“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;

“parties to a marriage” means a husband and wife and include a couple;

“primitive streak” means a primitive streak 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 a facilitated process or through natural means.

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

“surrogate mother” means a woman who has agreed to carry a pregnancy to term 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 carry children.

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.

PART II—THE ASSISTED REPRODUCTIVE TECHNOLOGY AUTHORITY

4. (1) There is established an Authority known as the Assisted Reproductive Technology Authority.

Establishment of the Authority.

(2) The Authority shall be a body corporate, with perpetual succession and a common seal and shall be capable, in its corporate name, of—

- (a) suing and being sued;
- (b) taking, purchasing or otherwise acquiring, holding or disposing of movable or immovable property;

- (c) entering into contracts;
- (d) borrowing money; and
- (e) doing or performing all such other acts or thing necessary for the proper performance of its functions under this Act.

(3) The Authority may establish such branches or organs as it may deem necessary for the effective and proper discharge of its function under this Act.

5. The functions of the Authority shall be to—

Functions of
the Authority.

- (a) develop standards, regulations and guidelines on assisted reproductive technology;
- (b) advice 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) undertake 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) grant, vary, suspend and revoke licenses;
- (g) keep under review information about embryos and any subsequent development of embryos;
- (h) provide advice and information to persons receiving assisted reproductive technology treatment including persons providing gametes or embryos under this Act;
- (i) disseminate information to the public on reproductive health that may relate or affect assisted reproductive technology;
- (j) establish and maintain a confidential national database on persons receiving assisted reproductive technology treatment services or providing gametes or embryos for use;

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

6. (1) The Authority shall have all powers necessary for the proper performance of its functions under this Act.

Powers of the Authority.

(2) Without prejudice to the generality of the foregoing, the Authority shall have power to—

- (a) control, supervise and administer the assets of the Authority in such manner as best promotes the purpose for which the Authority is established;
- (b) receive any grants, gifts, donations or endowments and make legitimate disbursements there from;
- (c) levy fees for services rendered by the Authority as may be determined from time to time by the Board;
- (d) open such banking accounts for the funds of the Authority as may be necessary;
- (e) enter into association with such other bodies or organizations within or outside Kenya as it may consider desirable or appropriate in furtherance or for the performance of its functions under this Act;
- (f) perform or undertake any other activity that may be necessary for the fulfillment of any of the functions of the Authority under this Act.

7. The management of the Authority shall vest in a Board of the Authority which shall comprise of—

Board of the Authority.

- (a) a chairperson appointed by the President and approved by the National Assembly;
- (b) the Principal Secretary in the Ministry for the time being responsible for finance or a representative designated in writing by the Principal Secretary;
- (c) the Principal Secretary in the Ministry for the time being responsible for health or a representative designated in writing by the Principal Secretary;
- (d) seven persons appointed by the Cabinet Secretary of whom—
 - (i) two shall be medical doctors, a woman and a man who possess proven knowledge and experience in reproductive health, nominated by the Kenya Medical Practitioners and

Dentist Board;

- (ii) two shall be lawyers, a woman and a man, who have actively contributed to the promotion of the rights and welfare of women and children nominated by the Law Society of Kenya;
- (iii) one shall be a representative of the Kenya National Human Rights and Equality Commission;
- (iv) one man and one woman, who are not affiliated to the organizations appearing in sub paragraphs (i), (ii) or (iii); and
- (e) the Director of the Authority, who shall be the Secretary to the Board.

8. The Chairperson and the members of the Board appointed under paragraph (d) (i) (ii) and (iii) of section 7 shall hold office for a term of three years and shall be eligible for re-appointment for one further term of three years.

Term of office.

9. The conduct and regulation of the business and affairs of the Board shall be as provided in the First Schedule.

Conduct of business and affairs of the Board.

10. The functions of the Board shall be to—

Functions of the Board.

- (a) formulate the policies of the Authority;
- (b) carry out the objects and functions of the Authority;
- (c) provide overall directions on effective coordination of the operations of the Authority; and
- (d) do anything incidental or conducive to the performance of any of the preceding functions.

11. (1) There shall be a Director of the Authority who shall be appointed by the Board upon such terms and conditions as the Board may determine.

Director of the Authority.

(2) The Director shall—

- (a) be an *ex-officio* member of the Authority but shall have no right to vote in any meeting of the Authority;
- (b) be the secretary to the Authority;

- (c) be responsible for the administration and day to day management of the affairs of the Authority;
- (d) ensure the maintenance of efficiency and discipline by all staff of the Authority; and
- (e) perform such other functions as may be assigned by Board.

12. The Board may appoint such officers, agents and other staff as are necessary for the efficient discharge of its functions under this Act and upon such terms and conditions as the Board may determine.

Staff of the Authority.

13. The Board may engage experts or consultants as it considers appropriate, to assist in the discharge of the functions of the Authority.

Experts and consultants.

14. The Board shall pay its members and staff such remuneration or allowances as it may determine upon the advice of the Salaries and Remuneration Commission.

Remuneration of Board members and staff of the Authority.
Delegation by the Authority

15. The Board may, by resolution either generally or in any particular case, delegate to any committee of the Authority or to any officer, member of staff or agent of the Authority, the exercise of any of the powers or the performance of any of the functions or duties of the Authority under this Act.

16. (1) No act or omission by a member of the Board or by an officer, employee, agent or servant thereof shall, if the act or omission was done *bona fide* for the purposes of executing a function, power or duty under the Act, render such member, officer, employee, agent or servant personally liable to any action, claim or demand whatsoever.

Protection from personal liability.

(2) The provisions of subsection (1) shall not relieve the Authority of the liability to pay compensation or damages to any person for any injury to him, his property or any of his interests caused by the exercise of any power conferred by this Act or by any other written law or by the failure, whether wholly or partially, of any works.

17. (1) The common seal of the Authority shall be kept in such custody as the Authority may direct and shall not be used except on the order of the Authority.

The seal.

(2) Affixing of the common seal of the Authority shall be authenticated by the signature of the chairperson and the Director on any document not required by law to be made under seal and all decisions of the Authority may be

authenticated by the signatures of the Chairperson and the Director.

(3) Notwithstanding the provisions of subsection (2), the Authority shall, in the absence of either the Director or the chairperson in any particular matter, nominate a member to authenticate the seal of the Authority on behalf of either the chairperson or the Director.

(4) A deed, instrument, contract or other document executed in accordance with sub-section (2) shall bind the Authority.

PART III – PROHIBITED ACTIVITIES

18. A person shall not, create, keep or use an embryo except as provided under this Act.

Use of embryo.

19. 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.

20. 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.

21. A person shall undertake assisted reproductive technology only for procreation purposes.

Assisted reproductive technology for procreation purposes.

22. 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.

23. 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 purposes.

24. 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.

25. 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.

Gametes obtained from minor.

26. The Authority shall not issue a license that allows-

Authority 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;
- (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 a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo; or
- (f) any form of human cloning.

27. 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 in a woman except in pursuance of a license as provided for under this Act.

PART IV—RIGHTS OF PARENTS DONORS, AND CHILDREN

28. 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 assisted reproductive process takes place within five years of the death of the man; and
- (b) the man had consented to parentage and the artificial insemination takes place within five years of the death of the man.

29. 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;
- (c) applies whether the woman was in Kenya or elsewhere at the time of the assisted reproductive process.

30. 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.

31. (1) A woman of twenty-five years or more 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 and shall relinquish all parental rights at birth over the child unless a contrary intention is proved.

32. (1) Parties to a marriage 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) The form shall indicate the names of the parents of the child to be born through assisted reproductive process.

(3) 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.

(4) 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.

(5) 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

PART V—ACCESS TO INFORMATION

33. The Authority 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 eighteen may by notice to the Authority require the Authority to—

Provision of information by the Authority.

- (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 Authority shall comply with the request of the applicant made under section 34 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 Authority 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 Authority was not required to give the information.

35. (1) The Authority 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 Authority requesting the Authority to give the information and the Authority 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 Authority seeking to verify whether a man is or is not the father of a child and the Authority shall comply with the request made by the government agency unless it appears to the Authority that there is not sufficient reason to seek for that information.

Information from the Authority.

(2) Where the government agency is aggrieved by the decision of the Authority, 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 Authority shall not disclose any information which the person holds or has held as a member or employee of the Authority.

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 Authority 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 Authority;
- (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.

PART VI—LICENSING

38. The Authority shall, in accordance with this Act issue, vary, revoke or renew a licence in relation to activities under this Act. Licence.

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

40. (1) An application for a licence under this section shall be made to the Authority 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 Authority 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 Authority 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 3, the Authority shall inspect once in each calendar year, any premises where assisted reproduction process is to be carried and a report made on the inspection.

(3) The Authority may not inspect a premise in any particular year if the Authority considers the inspection in that year unnecessary.

42. (1) The Authority 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 Authority, 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 Authority 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 Authority;
- (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 Authority; and
- (f) the Authority 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 Authority and any government bodies on—

- (a) the persons to whom assisted reproductive technology services are provided;
- (b) the kind of assisted reproductive technology

services provided;

- (c) the persons whose gametes are kept or used for the purposes of assisted reproductive technology services
- (d) the persons whose gametes have been used in bringing about human procreation.
- (e) such other matters as the Authority 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 Authority.

(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.

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) no gametes or embryos shall be kept in storage for longer than the statutory storage period, and
- (e) 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 Authority 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 Authority the Authority 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 Authority may grant a licence to any person by way of renewal whether on the same or different terms.

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

(4) The Authority shall not grant a licence 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 Authority with the approval of the Cabinet Secretary.

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

(7) The Authority 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 Authority 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 Authority 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 Authority has power to revoke a license under subsection (1), the Authority may vary any terms of the licence.

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

(4) The Authority 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 Authority 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 Authority 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 Authority under this Act.

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

Appeal to the Authority

- (a) the applicant may appeal to the Authority within 30 days of the date on which the decision was served on the applicant; and
- (b) the Authority may make such determination on the appeal as it thinks fit.

(2) The Authority 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.

(3) The functions of the Authority on an appeal under this section cannot be discharged by any committee, member or employee of the Authority and, for the purposes of the appeal the quorum shall not be less than five.

48. Where the Authority determines under section 46 of this Act—

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;
- (c) the person on whom notice of the determination was served may appeal to the High Court.

49. (1) Where the Authority—

Temporary suspension of a licence.

- (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, the Authority may by

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

(2) The Authority 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 Authority 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 Authority may, by a further notice to that person, renew or further renew the notice under subsection (1) specified in the renewal notice.

PART VII — FINANCIAL PROVISIONS

50. The funds of the Authority shall consist of—

Funds of the Authority.

- (a) monies allocated by Parliament for the purposes of the Authority;
- (b) such monies or assets as may accrue to the Authority in the course of the exercise of its powers or the performance of its functions under this Act;
- (c) gifts, grants or donations as may be given to the Authority;
- (d) monies that may be borrowed by the Board of Management for the discharge of the functions of the Authority;
- (e) monies from any other source provided for the Authority.

51. The Financial year of the Authority shall be the period of twelve months ending on the thirtieth day of June in each year.

Financial year

52. (1) At least three months before the commencement of each financial year, the Authority shall cause to be prepared estimates of the revenue and expenditure of the Authority of that year.

Annual Estimates

(2) The annual estimates shall make provisions for all estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for—

- (a) the payment of the salaries, allowances and other

charges in respect of the staff of the Authority;

- (b) the payment of pensions, gratuities and other charges in respect of benefits which are payable out of the funds of the Authority;
- (c) the acquisition and maintenance of the buildings and grounds of the Authority;
- (d) the funding of training, research and development activities of the Authority;
- (e) the proper maintenance, repair and replacement of any installation and of the equipment and other movable property of the Authority;
- (f) the creation of such funds to meet future or contingent liabilities in respect of benefits, insurance or replacement of buildings or installation or equipment and in respect of such other matters as the Authority may think fit.

(3) The annual estimates shall be approved by the Authority before the commencement of the financial year to which they relate, and shall be submitted to the Cabinet Secretary for approval and after the Cabinet Secretary has given approval, the Authority shall not increase any sum provided in the estimates without written consent of the Cabinet Secretary.

(4) No expenditure shall be incurred for the purposes of the Authority except in accordance with the annual estimates approved under subsection (3), or in pursuance of an authorization of the Authority given with the prior approval of the Cabinet Secretary.

53. (1) The Authority shall cause to be kept all proper books and records or account of the income, expenditure, assets and liabilities of the Authority.

Accounts and
Audit.

(2) The Cabinet Secretary for the time being responsible for finance may prescribe the form of any book required to be kept under subsection (1) and unless a form has been prescribed, a form suitable for the purpose shall be used.

(3) Within a period of three months after the end of each financial year, the Authority shall submit to the Auditor General the accounts of the Authority in respect of that year

together with—

- (a) a statement of the income and expenditure of the Authority during the financial year;
- (b) a statement of the assets and liabilities of the Authority on the last day of that financial year.

(4) The accounts of the Authority shall be audited and reported upon by the Auditor-General in accordance with the provisions of the Public Audit Act, 2015.

54. (1) The Authority may invest any of its funds in securities in which for the time being trustees may by law invest trust funds or in any other securities which the Treasury may, from time to time approve.

Investments of Funds.

(2) The Authority may place on deposit with such bank or banks or financial institutions as it may determine, any moneys not immediately required of the purposes of the Authority.

55. (1) The Authority shall cause an annual report to be prepared for each financial year.

Annual Reports.

(2) The Authority shall submit the annual report to the Cabinet Secretary within three months after the end of the year to which it relates;

(3) The annual report shall contain, in respect of the year to which it relates—

- (a) the financial statements of the Authority;
- (b) a description of the activities of the Authority;
- (c) such other statistical information as the Authority considers appropriate relating to the work of the Authority;
- (d) any other information relating to the functions that the Authority considers necessary.

(4) The Cabinet Secretary shall, within thirty days, after receiving the annual report, transmit it to the National Assembly.

56. The Authority may, any time, submit a special report to the National Assembly through the Cabinet Secretary with respect to any aspect of the functions of the

Special reports

Authority which the Authority considers should, in the national interest, be brought to the attention of the National Assembly.

PART VIII—MISCELLANEOUS PROVISIONS

57. (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) A person who commits an offence under subsection (1) shall, upon conviction, be liable to a fine not exceeding five hundred thousand shilling or to a term not exceeding five years, or to both.

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

PART IX—PROVISIONS ON DELEGATED POWERS

59. The Cabinet Secretary, in consultation with the Authority 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 the number of times that a patient can be given assisted reproductive services;
- (e) for settling disputes arising out of assisted reproduction;
- (f) for the maintenance for records;
- (g) regarding rights and duties of patients, donors surrogates and children;
- (h) 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;

- (i) in respect of the number of children that may be created from the gametes of one donor through the application of assisted reproduction procedures;
- (j) in respect of the terms and conditions of licenses;
- (k) in respect of the qualifications for licenses.
- (l) in respect of the issuance, amendment, renewal, in respect of suspension, restoration and revocation of licenses;
- (m) in respect of the information to be provided in respect of applications for a license or for the renewal or amendment of a license;
- (n) in respect of the identification and labeling of human reproductive materials and embryos from assisted reproductive process used in treatment services;
- (o) in respect of the collection, use and disclosure of information regarding assisted reproduction processes;
- (p) in respect of counseling services;
- (q) in respect of research relating to assisted reproductive technology treatment, services and products.

SCHEDULE (s.9)

PROVISIONS AS TO THE CONDUCT OF BUSINESS AFFAIRS OF THE BOARD

1. (1) A member appointed to the Board under paragraphs (a) and (e) of section 7 shall cease to be a member if the member-

Vacation of office.

- (a) serves the Cabinet Secretary with written notice of resignation;
- (b) is absent without justifiable reason, from three consecutive meetings of the Board;
- (c) is convicted of a criminal offence and is sentenced to imprisonment for a term exceeding six months with or without the option of a fine; or
- (d) is incapacitated by prolonged physical or mental illness from performing the duties of the office of a member of the Board.

2. (1) The Board shall hold such number of meetings at such places and at such times as the Board shall consider necessary for the proper discharge of its functions.

Meeting of the Authority.

(2) Notwithstanding sub-paragraph (1) the Board shall meet not less than four times in each financial year.

(3) At least a fourteen days notice shall be given prior to any meeting of the Board

3. The chairperson or any three members may call a special meeting whenever it is expedient for the transaction of the business of the Board by giving not less than seven days notice to the members.

Special meeting

4. (1) The chairperson shall preside at all meetings of the Board

Presiding at meetings.

(2) In the absence of the chairperson at a meeting, the vice-chairperson shall preside at that meeting of the Board.

(3) In the absence of the chairperson and the vice-chairperson at a meeting, the members present shall elect a member to preside at that meeting of the Board.

5. The quorum for the conduct of business at a meeting of the Board shall be the majority of the members of the Board.

Quorums

6. (1) A decision on any matter before the Board shall be by a majority of votes of the members present and voting.

Voting.

(2) In case of an equality of votes, the chairperson or the person presiding shall have a casting vote.

7. Proceedings of the Board shall not be invalid by reason only of a vacancy in the membership of the Board or by reason of a defect in the appointment of a member.

Vacancies and defects in appointment

8. The minutes of the Board shall be kept in such a manner as the Board directs, and, on the written request of the Cabinet Secretary, shall be made available to him or any person nominated by him.

Minutes.

9. The Board may establish such committees as may be necessary for the performance of the functions of the Board.

Committees of the Authority

10. Subject to the provisions of the Schedule, the Board shall regulate its own procedure.

Powers of the Authority to regulate its own procedure.
Code of conduct

11. Within six months of the commencement of this Act, the Board shall establish a code of conduct for the practice and conduct of assisted reproduction.

12. If a member of the Board is directly or indirectly interested in a contract or other matter before the Board and is present at a meeting of the Board at which the contract, proposed contract or other matter is the subject of consideration, that member shall, as soon as is practicable after the commencement of that meeting, disclose the fact.

Disclosure of interest.

13. The Director shall keep a record of all proceedings and meetings of the Board

Records

MEMORANDUM OF OBJECTS AND REASONS

The principal object of the Bill is to regulate rights and obligations relating to assisted reproductive technology. The Bill aims to regulate the use of assisted reproductive technologies to aid individuals or couples that have challenges conceiving due to factors associated with infertility. Furthermore, the Bill aims to regulate the qualifications of health practitioners who administer assisted reproductive technology in order to protect recipients of the latter services.

In addition, the Bill contains provisions that define rights touching on among others issues relating to consents preceding assisted reproduction; handling of embryos resulting from assisted reproductive technology; protection of the identity, status and welfare of children borne out of assisted reproduction; and duties of persons who undergo assisted reproduction and their legal status as parents.

The Bill establishes an Assisted Reproductive Technology Authority to regulate the processes, licensing, standards, research, and infrastructure relating to assisted reproductive technology. The legislative scheme of the Bill has been modelled in a manner that addresses a balance between the need for regulation of ethics and advancement of modern science and technology.

PART I of the Bill contains preliminary provisions;

PART II of the Bill provides for establishment of the Assisted Reproductive Technology Authority regulate the processes, information, licensing, standards, research and infrastructure relating to assisted reproductive technology;

PART III of the Bill provides for prohibited activities relating to assisted reproductive technology;

PART IV of the Bill provides for the rights of parents donors, and children;

PART V of the Bill provides for access to information contained in the assisted reproductive technology register;

PART VI of the Bill provides for licensing to administer various aspects touching on assisted reproductive technology;

PART VII of the Bill contains provisions relating to budgeting, expenditure, accounting and reporting of finances of the Assisted Reproductive Technology Authority; and

PART VIII of the Bill contains miscellaneous provisions relating to offences; and

PART IX of the Bill contains provisions on delegated powers

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

The Bill 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 not 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 27th March, 2019.

MILLIE ODHIAMBO MABONA,
Member of Parliament.

