A BILL

FOR

AN ACT TO AMEND THE NATIONAL HEATH ACT TO PROVIDE FOR REGULATION OF ASSISTED BIRTH TECHNOLOGY, FOR SAFE AND ETHICAL PRACTICE OF ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES AND FOR RELATED MATTERS

Sponsored by Hon. Segun Adekola

[ ] Commencement

BE IT ENACTED by the National Assembly of the Federal Republic of Nigeria as follows:

1. The National Health Act 2016 (In this Bill referred to as "The Principal Act") is amended as set out in this bill. Amendment of National Health Act 2015

2. There is hereby inserted after the existing Part VI, the following new PART VIA as follows: Insertion of new Part VIA

PART VIA - REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY

59.-(1) The Federal Ministry of Health shall, subject to provisions of this Act, rules and regulations made there under, take measures to develop new policies in the area of Assisted Reproductive Technology and to accredit and regulate of services of Assisted Reproductive Technology Clinics and Banks in the country.

(2) Without prejudice to the generality of the foregoing provisions, the measures referred to in sub-section (1) may provide for all or any of the following matters, namely:

(a) the regulation in respect of the minimum requirements related to staff and physical infrastructure for the various categories of assisted reproductive technology clinics and assisted reproductive technology banks;

(b) the regulations in respect of permissible assisted reproductive technology procedures;

(c) the regulations in respect of selection of patients for assisted reproductive technology procedures;

(d) the regulation in respect of the encouragement and promotion of training and research in the field of assisted reproduction;

(e) (i) the regulation in respect of counseling and providing patients with all necessary information and advice on various aspects of assisted reproductive technology procedures;

(ii) the regulation describing duties and responsibilities of the counsellor with special reference to potential surrogate mother and oocyte donor to explore the range of outcomes and possible long term effects and to evaluate her psychological risks and vulnerabilities as well as the possible effects of surrogacy and oocyte donation on their existing relationship and on any existing child/children.

(f) the regulation in respect of the ways and means of disseminating information related to infertility and assisted reproductive technologies to various sections of the society;

(g) the regulations in respect of research on human embryos;

(h) the regulation in respect of the proforma for obtaining information from donors of gametes and surrogate mothers, consent forms for various procedures, and contracts or agreements between the various parties involved;

(i) such other functions as may be prescribed.

60.-(1) With effect from the commencement of this act the ministry may, by notification, establish for the purposes of this Act, a National Registry to be called the National Registry of Assisted Reproductive Technology Clinics and Banks in Nigeria.

(2) The National Registry shall act as a Central data- base in the country and through which details of all the Assisted Reproductive Technology Clinics and Assisted Reproductive Technology Banks of the country including nature and types of services provided by them, outcome of the services and other relevant information shall be obtained on regular basis.

(3) The National Registry shall assist in the accreditation, supervision and regulation of the Assisted Reproductive Technology Clinics and Assisted Reproductive Technology Banks by providing the data generated from the Central database of the Registry.

(4) The Ministry shall in conjunction with the National Registry shall develop an appropriate curriculum for training programmes in the area of clinical embryology, andrology, counselling and other related fields and shall run regular training programmes in these areas and other related fields.

(5) The data generated from the National Registry shall be utilised for making policies, guidelines and shall help in identifying new research areas and conducting research in the area of assisted reproduction and other related fields in the country.

61. The Ministry shall have power to inspect any premises using Assisted Reproductive Technology without prior intimation.

62. No assisted reproductive technology clinic and assisted reproductive technology bank shall practice any aspect of assisted reproductive technology, or use any premises for such purposes, without registering as the assisted reproductive technology clinic or assisted reproductive technology bank with the Ministry:

Provided that any assisted reproductive technology clinic or assisted reproductive technology bank which is carrying out the work of assisted reproductive technology on or before the date of commencement of this Act, may continue to do so until the certificate of registration is granted or declined to it by the Ministry and a unique registration number to be given or declined by the Ministry under this Act:

Provided further that such assisted reproductive technology clinic and assisted reproductive technology bank shall, within a period of ninety days from the date of the commencement of this Act, make an application under this part for registration as an assisted reproductive technology clinic or assisted reproductive technology bank under this Act:

Provided also that the Ministry shall, within a period of ninety days from the date of such application, either issue the certificate of registration or reject the application under section 62.

63.-(1) All assisted reproductive technology clinics and the assisted reproductive technology banks shall make an application to the Ministry for the registration of the assisted reproductive clinic or assisted reproductive bank within such period and in such form accompanied by such fee as may be prescribed.

(2) Every application under sub-section (1) shall be accompanied by the following, namely:

(a) bio-data of all the faculty members of the clinic or bank including Director or in-charge of the clinic or bank;

(b) copies of the degrees and certificates of all the faculty members of the clinic or bank including Director in-charge of the clinic or bank;

(c) such other information and documents as may be prescribed.

(3) Any assisted reproductive technology clinic or assisted reproductive technology bank by whatsoever name called, may apply to the Ministry for registration to operate the Assisted Reproductive Technology clinic or assisted reproductive technology bank in accordance with the procedure and criteria laid down in this Act.

(4) Every application for registration by an assisted reproductive technology clinic or assisted reproductive technology bank under sub-section (l) shall contain the particulars of the applicant including all details of techniques and procedures of assisted reproductive technology practiced before enactment of this Act and to be practised after coming into force of this Act at such clinics or banks.

(5) Notwithstanding anything contained in this Act or any of the rules made there under, no assisted reproductive technology clinic and assisted reproductive technology bank performing any of the functions under this part or any other advanced diagnostic, therapeutic shall practice any aspect of such

diagnosis, therapy without a certificate of accreditation issued by the Ministry.

(b) reject the application for reasons to be recorded in writing, if such application does not conform to the provisions of this Act:

64.-(1) On receipt of the application under this part, the ministry shall within a period of ninety days;

(a) grant registration subject to the provisions of this Act and the rules and the regulations made there under;

Provided that no application unless the applicant has opportunity of being heard, shall be rejected been given an

(2) No registration shall be granted unless the ministry, or such authorised person or persons acting on its behalf, have inspected the premises and certified that the premises of the applicant is equipped with the requisite facilities for carrying out the procedures related to the assisted reproductive technology and is fit for the same.

(5) The registration granted under this section shall be valid for a period of three years from the date of registration granted by the ministry.

65. The registration granted under section 62 may be extended by the ministry on an application made by the applicant, under such conditions as may be prescribed, in such form and on payment of such fee as may be specified by the regulations made by the ministry.

66.-(1) The ministry may, on receipt of a complaint in this behalf, revoke the registration granted under section 62, after being satisfied that:

(a) the applicant makes wilful default in doing anything required of him by or under this Act or the rules or the regulations made there under;

(b) the applicant violates any of the terms or conditions of the approval given by the ministry;

(c) the applicant is involved in any kind of unfair practice or irregularities.

(2) The registration granted to the applicant under section 62 shall

not be revoked unless the ministry has given to the applicant not less than thirty days notice in writing, stating the grounds on which it is proposed to revoke the registration, and has considered any cause shown by the holder of registration within the period of that notice against the proposed revocation.

(3) The ministry may, instead of revoking the registration under sub-section (1), permit it to remain in force subject to such further terms and conditions as it thinks fit to impose in the interest of patients, and any such terms and conditions so imposed shall be binding upon the holder of registration.

(4) Upon the revocation of the registration, the ministry:

(a) shall debar the holder of registration from operating the assisted reproductive technology clinic or assisted reproductive technology bank and displaying his name in the list of defaulters on its website;

(b) to protect the interest of patients or in the public interests, issue such directions as it may deem necessary.

(5) Notwithstanding anything contained in sub-sections (1), (2), (3) and sub-section (4), if the ministry is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any assisted reproductive technology clinic without issuing any such notice referred to in sub-section (2).

67. The ministry shall have the power to inspect, with or without prior notice on a working day during working hours, any premises relating to assisted reproductive technology or call for any document or material in the discharge of its powers and functions.

68.-(1) The assisted reproductive technology clinics and assisted reproductive technology banks shall ensure that patients, donors of gametes and surrogates are eligible to avail of assisted reproductive technology procedures under the criteria specified by the rules under this Act and that they have been medically tested for such diseases, sexually transmitted or otherwise, including HIV/AIDS as may be specified and all other

communicable diseases which may endanger the health of the commissioning couple, or anyone of them, surrogate or child.

(2) It shall be the responsibility of an assisted reproductive technology clinic to obtain, from assisted reproductive technology bank, all relevant information, other than the name, personal identity and address, of possible gamete donors, and assist the commissioning couple desirous of the donation, to choose the donor.

(3) When an assisted reproductive technology bank receives a request from an assisted reproductive technology clinic for a donor oocyte, a responsible member of the staff of the assisted reproductive technology bank shall accompany the particular donor to the assisted reproductive technology clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall under no circumstances reveal the identity of the donor to the recipient couple or to anyone else and ensure that all its staff is made aware of the fact that any step leading to disclosure of the identity of the oocyte donor (i.e., the name and address) to the recipient couple or to anyone else, shall amount to an offence punishable under this Act, except in case of a medical emergency or in pursuance of an order issued by a competent court.

(4) Either of the parties seeking assisted reproductive technology treatment or procedures shall be entitled to specific information in respect of donor of gametes including height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, including HIV/AIDS:

Provided that the parties shall not be entitled to specific information in respect of the individual identity, name and address of the donor.

(5) The assisted reproductive technology clinics shall obtain donor gametes from assisted reproductive technology banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, including HIV / AIDS as may be prescribed and all other

communicable diseases which may endanger the health of the commissioning couple, or anyone of them, surrogate or child.

(6) The assisted reproductive technology clinics shall provide professional counselling to commissioning couple about all the implications and chances of success of assisted reproductive technology procedures in the clinic in Nigeria and internationally, and shall also inform commissioning couple of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the commissioning couple arrive at a informed decision that would be most likely to be the best for the commissioning couple.

(7) The assisted reproductive technology clinics shall make commissioning couple, as the case may be, aware of the rights of a child born through the use of assisted reproductive technology.

(8) The assisted reproductive technology clinics shall explain to commissioning couple, as the case may be, the choice or choices of treatment available to them and the reason or reasons for recommending a particular treatment, and shall clearly explain the advantages, disadvantages, limitations and cost of any recommended or explained treatment or procedure.

(9) The assisted reproductive technology clinics and Assisted Reproductive Technology Banks shall ensure that information about clients, donors and surrogate is kept confidential and that information about assisted reproductive technology treatment shall not be disclosed to anyone other than a central database to be maintained by the National Registry for Assisted Reproductive Technology Clinics except in a medical emergency at the request of the person or persons or the closest available relative of such person or persons to whom the information relates, or by an order of a court of competent jurisdiction.

(10) No assisted reproductive technology clinic shall consider conception by surrogacy for patients for whom it shall normally be possible to

carry a baby to term:

Provided that where it is determined that such conception may be unsafe or may lead to undesirable medical implications, the use of surrogacy may be permitted.

(11) The assisted reproductive technology clinics shall provide to commissioning couple, as the case may be, a pre-stamped self-addressed envelope to inform the clinic of the results of the assisted reproductive technology procedure performed for the commissioning couple.

(12) No assisted reproductive technology clinic shall obtain or use sperm or oocyte donated by a relative or known friend of either of the parties seeking assisted reproductive technology treatment or procedures.

(13) (a) Every assisted reproductive technology clinic and Assisted Reproductive Technology Banks shall establish a mechanism to look into complaints in such manner as may be prescribed under this act;

(b) An appropriate provision shall be made for the complaints relating to ART treatment or procedures against the ART Clinic and Bank under the Rules. Simultaneously a provision shall also be made, to review and for speedy disposal of these complaints pending against such clinics and banks.

(14) (a) No assisted reproductive technology procedure shall be performed on a woman below the age of twenty three years and above the age of fifty years and the concerned Gynaecologist shall furnish certificate indicating that the woman is medically fit to opt for the ART services;

(b) No assisted reproductive technology procedure shall be performed on a man below the age of twenty three years and above the age of fifty five years.

(15) All assisted reproductive technology clinics shall issue to the infertile commissioning couple a discharge certificate stating details of the assisted reproductive technology procedure performed on the commissioning couple and its outcome.

69.-(1) No assisted reproductive technology clinic shall perform any treatment or procedure of assisted reproductive technology without the consent in writing of all the parties seeking assisted reproductive technology to all possible stages of such treatment or procedures including the freezing of human embryos.

(2) No assisted reproductive technology clinics and assisted reproductive technology banks shall freeze any human embryos and/or gametes 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.

(3) No assisted reproductive technology clinic shall use any human reproductive material to create a human embryo or use an in vitro human embryo for any purpose without the specific consent in writing of all the parties to whom the assisted reproductive technology relates.

(4) The consent of any of the parties obtained under this section may be withdrawn at any time before the human embryos or the gametes are transferred to the concerned woman's uterus.

70.-(1) All assisted reproductive technology clinics and assisted reproductive technology banks shall maintain detailed records, in such manner as may be prescribed, of all donor oocytes, sperm or embryos used, the manner and technique of their use, and the commissioning couple or surrogate, in respect of whom it was used.

(2) All assisted reproductive technology clinics shall, put on line all information available to them in regard to progress of the patient, such as biochemical and clinical pregnancy, within a period of seven days of the information becoming available, withholding the identity of the patient.

(3) The records maintained under sub-section (1) shall be maintained for at least a period of ten years, upon the expiry of which the assisted reproductive technology clinic and assisted reproductive technology bank

shall transfer the records to a central database of the National Registry of Assisted Reproductive Technology Clinics.

(4) In the event of the closure of any assisted reproductive technology clinic and assisted reproductive technology bank before the expiry of the period of ten years under sub-section (2), the assisted reproductive technology clinic and assisted reproductive technology bank shall immediately transfer the records to a central database of the National Registry of Assisted Reproductive Technology Clinics and

71.-(1) The assisted reproductive technology clinics shall harvest oocytes in accordance with such regulations made under this act

(2) The number of oocytes or embryos that may be placed in a woman during anyone treatment cycle shall be such as may be specified by the regulations made under this act

(3) No woman should be treated with gametes or embryos derived from the gametes of more than one man or woman during anyone treatment cycle.

(4) An assisted reproductive technology clinic shall never mix semen from two individuals before use.

(5) Where a multiple pregnancy occurs as a result of assisted reproductive technology, the concerned assisted reproductive technology clinic shall inform the patient immediately of the multiple pregnancy and its medical implications and may carry out foetal reduction after appropriate counselling.

(6) The collection of gametes from a person whose death is imminent shall only be permissible if such person's spouse intends to avail assisted reproductive technology to have a child.

(7) No assisted reproductive technology clinic shall use ova that are derived from a foetus, in any process of in vitro fertilisation.

(8) No assisted reproductive technology clinic shall utilise any semen, whether from an assisted reproductive technology bank or

otherwise, for any aspect of assisted reproductive technology unless such semen is medically analysed in such manner as may be prescribed.

72.-(1) No assisted reproductive technology clinic shall offer to provide a couple with a child of a pre-determined sex.

(2) It is prohibited for anyone to do any act, at any stage, to determine the sex of the child to be born through the process of assisted reproductive technology.

(3) No person shall knowingly provide, prescribe or administer anything that would ensure or increase the probability that an embryo shall be of a particular sex, or that would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.

(4) No assisted reproductive technology clinic shall carry out any assisted reproductive technology procedure to separate, or yield fractions enriched in sperm of X or Y variations.

(5) The collection of blood samples from pregnant woman and subjecting the blood sample for sex selection in any form both within the country and outside the country shall be prohibited.

73.-(1) All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules made under shall be preserved for a period of ten years and after which the records shall be transferred to the National Registry of Records to be maintained by assisted reproductive technology bank:

Provided that, if any criminal or other proceedings are instituted against any Assisted Reproductive Technology Clinics or Assisted Reproductive Technology Banks, the records and all other documents of such Assisted Reproductive Technology Clinics and Assisted Reproductive Technology Banks shall be preserved till the final disposal of such proceedings.

(2) Where an assisted reproductive technology bank closes before the expiry of the period of ten years, the records shall be immediately transferred to the National Registry of Assisted Reproductive Technology Clinic and Banks

74.-(1) The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside Nigeria is prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the Ministry

(2) The sale of gametes, except for use by an assisted reproductive technology clinic for treating infertility, and the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India is prohibited.

75.-(1) Subject to the provisions of this Act and the rules and regulations made there under, the option of assisted reproductive technology, except option of surrogacy shall be available to all married infertile couple.

(2) In case the assisted reproductive technology is used by a couple, there must be written consent from both the parties.

(3) The parents of a minor child have the right to access information about the donor, other than the name, identity or address of the donor, or the surrogate to the extent necessary for the welfare of the child.

(4) All information about the patients shall be kept confidential and information about Assisted Reproductive Technology procedures done on them shall not be disclosed to anyone other than the Ministry, except with the consent of the person or persons to whom the information relates, in case of a medical emergency or by an order of a competent court of jurisdiction.

76.-(1) Subject to the provisions of this Act, all information about the donors shall be kept confidential and information about gamete donation shall not be disclosed to anyone other than the Ministry except with the consent of the person or persons to whom the information relates, in case of a medical emergency or by an order of a court of competent jurisdiction.

(2) Subject to the provisions of this Act, the donor shall have the right to decide what information may be passed on and to whom, except in the case of an order of a court of competent jurisdiction.

(3) A donor shall relinquish all parental rights over the child or children which may be conceived from his or her gamete.

(4) No assisted reproductive technology procedure shall be conducted on or in relation to any gamete of a donor under this Act unless such donor has obtained the consent in writing of his or her spouse, if there, to such procedure.

(5) The identity of the recipient shall not be made known to the donor.

77.-(1) No assisted reproductive technology clinic, or assisted reproductive technology bank or agent thereof, shall issue, publish, distribute, communicate or caused to be issued, published, or distributed or communicated any advertisement in any manner including internet, regarding facilities of pre-natal determination of sex.

(2) Any person who contravenes the provisions of this section or any provisions of any section under this part shall be liable on conviction to:

(a) In the case of an individual, to imprisonment of a term not exceeding Five years or to fine not exceeding 3 million naira; and

(b) In the case of a, Hospital or medical clinic a fine not exceeding N10,000,000 and in addition the hospital or clinic shall be closed down.

(3) Where a Hospital or medical clinic commits an offence under this Section, any officer, director or agent who directed, authorized, assented to or acquiesced or participated in the commission of the offence is a party to and guilty of the offence and is liable on conviction to the punishment provided for the offence, whether or not the Hospital or medical Clinic has been prosecuted for or convicted of the offence.

(4) In any prosecution for an offence under Section, it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused, whether or not the employee or agent is identified or has been prosecuted for the offence.

(5) Whoever contravenes any of the provisions of this Act or any rules made there under, for which no penalty has been elsewhere provided in this

Act, shall be punishable on conviction to:

(a) In the case of an individual, to imprisonment of a term not exceeding Five years or to fine not exceeding 3 million naira; and

(b) In the case of a, Hospital or medical clinic a fine not exceeding N10,000,000 and in addition the hospital or clinic shall be closed down.

Renumbering of Sections

3. Renumber Sections 59, 60, 61, 62, 63, 64 and 65 of the principal Act as Sections 78, 79, 80, 81, 82, 83 and 84 respectively.

Citation

4. This Bill may be cited as the National Health Act (Amendment) Bill, 2016.

EXPLANATORY MEMORANDUM

The bill seeks to amend the National Heath Act to amongst other things provide for regulation of assisted birth technology/ in-vitro fertilization (ivf), to provide for the accreditation, regulation and supervision of assisted reproductive technology clinics and the assisted reproductive technology banks, for prevention of misuse of assisted reproductive technology, for safe and ethical practice of assisted reproductive technology.