A BILL

FOR

AN ACT TO PROVIDE A FRAMEWORK FOR THE REGULATION, DEVELOPMENT AND MANAGEMENT OF A NATIONAL HEALTH SYSTEM AND SET STANDARDS FOR RENDERING HEALTH SERVICES IN THE FEDERATION, AND OTHER MATTERS CONNECTED THEREWITH, 2014.

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} Commencement

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

PART 1 - RESPONSIBILITY FOR HEALTH AND ELIGIBILITY FOR HEALTH SERVICES AND ESTABLISHMENT OF NATIONAL HEALTH SYSTEM

1. (1) There is hereby established for the Federation the National Health System, which shall define and provide a framework for standards and regulation of health services, without prejudice to extant professional regulatory laws and which shall –

(a) encompass public and private providers of health services;

(b) promote a spirit of cooperation and shared responsibility among all providers of health services in the Federation and any part thereof;

(c) provide for persons living in Nigeria the best possible health services within the limits of available resources;

(d) Set out the rights and obligations of health care providers, health workers, health establishments and users; and

(e) Protect, promote and fulfil the rights of the people of Nigeria to have access to health care services.

(2) The National Health System shall include -

(a) the Federal Ministry of Health;

(b) The Ministry of Health in every state and the Federal Capital Territory Department responsible for Health;

(c) parastatals under the federal and state ministries of health;

(d) all local government health authorities;

(e) the ward health committees;

(f) the village health committees;

(g) the private health care providers;

(h) traditional health care providers; and

(i) alternative healthcare providers.

2. (1) The Federal Ministry of Health shall -

Functions of the Federal Ministry of Health.

(a) ensure the development of national health policy and issue guidelines for its implementation;

(b) collaborate with the states and local governments to ensure that appropriate mechanisms are set up for the implementation of national health policy;

(c) collaborate with national health departments in other countries and international agencies;

(d) promote adherence to norms and standards for the training of human resources for health;

(e) ensure the continuous monitoring, evaluation and analysis of health status and performance of the functions of all aspects of the National Health System;

(f) co-ordinate health and medical services delivery during national disasters;

(g) participate in inter-sectoral and inter-ministerial collaboration;

(h) conduct and facilitate health systems research in the planning, evaluation and management of health services;

(i) ensure the provision of tertiary and specialized hospital services;

(j) ensure and promote the provision of Quarantine and Port Health Services;

(k) determine the minimum data required to monitor the status and use of resources;

(I) promote availability of good quality, safe and affordable essential drugs, medical commodities, hygienic food and water; and

(m) issue guidelines and ensure the continuous monitoring, analysis and good use of drugs and poisons including medicines and medical devices.

(2) Without prejudice to the foregoing functions, the Federal Ministry of Health shall:-

(a) prepare strategic, medium term health and human resources plans annually for the exercise of its powers and the performance of its duties under this Act;

(b) ensure that the national health plans referred to in paragraph (a) of this subsection shall form the basis of—

(i) the annual budget proposal as required by the Federal Ministry of Finance; and

(ii) other governmental planning exercises as may be required by any other law;

(c) ensure that the national health plans shall comply with national health policy.

(d) ensure the preparation and presentation of an annual report of the State of health of Nigerians and the National Health System to the President and the National Assembly.

(3) The Federal Ministry of Health shall where necessary provide to State Ministries of Health—

(a) technical assistance in the development of state health policies and plans;

(b) commodities and technical materials, including methodologies, policies and standards for use in programme implementation including monitoring and evaluation; and

(c) other technical assistance as may be necessary.

(4) The Minister shall supervise the departments and parastatals of the Ministry to enable him carry out the functions assigned to the Ministry by this or any other Act.

(1) The Minister, in consultation with the National Council on Health may prescribe conditions subject to which categories of persons may be eligible for exemption from payment for health care services at public health establishments.

Eligibility for exemption from payment for health services in public health establishments.

and

Establishment

Health.

Composition of the

National Council on

(2) In prescribing any condition under subsection (1), the Minister shall have regard to:-

(a) the range of exempt health services currently available;

(b) the categories of persons already receiving exemption from payment for health services;

(c) the impact of any such condition on access to health services; and

(d) the needs of vulnerable groups such as women, children, older persons and persons with disabilities.

(3) Without prejudice to the prescription by the Minister in subsection 3(1), all Nigerians shall be entitled to basic minimum package of health services.

- 4. (1) There is hereby established the National Council on Health (in this Act referred to as "the National Council" or "Council") which shall consist of
 - (a) the Minister, who shall be the Chairman;
 - (b) the Minister of State for Health, if any;

(c) the Commissioners responsible for matters relating to Health in the States of the Federation; and

(d) the Secretary responsible for Health in the Federal Capital Territory, Abuja.

(2) The Permanent Secretary of the Federal Ministry of Health shall be the Secretary to the National Council.

- (3) The National Council shall meet at least once in a year.
- (4) The National Council shall have powers to regulate its proceedings.
- 5. (1) The National Council which shall be the highest policy making body in Nigeria on matters Functions of the relating to health, shall –

(a) have responsibility for the protection, promotion, improvement and maintenance of the health of the citizens of Nigeria, and the formulation of policies and prescription of measures necessary for achieving the responsibilities specified under this paragraph;

(b) offer advise to the Government of the Federation, through the Minister, on matters relating to the development of national guidelines on health and the implementation and administration of the National Health Policy;

(c) ensure the delivery of basic health services to the people of Nigeria and prioritize other health services that may be provided within available resources;

(d) advise the Government of the Federation on technical matters relating to the organization, delivery and distribution of health services;

(e) issue, and promote adherence to, norms and standards, and provide guidelines on health matters, and any other matter that affects the health status of people;

(f) identify health goals and priorities for the nation as a whole and monitor the progress of their implementation;

(g) promote health and healthy lifestyles;

(h) facilitate and promote the provision of health services for the management, prevention and control of communicable and non-communicable diseases;

(i) ensure that children between the ages of zero and five years and pregnant women are immunized with vaccines against infectious diseases;

(j) coordinate health services rendered by the Federal Ministry with health services rendered by the States, Local Government, Wards, and private health care providers and provide such additional health services as may be necessary to establish a comprehensive national health system;

(k) integrate the health plan of the Federal Ministry of Health and State Ministries of Health annually; and

(I) perform such other duties as may be assigned to the Council by the Minister.

(2) The National Council shall determine the time frames, guidelines and format for the formulation of the National and State Health Plans.

(3) The National Council shall be advised by the Technical Committee established in terms of this Bill.

6. (1) There is hereby established a Technical Committee of the National Council on Health (in this Bill referred to as "the Technical Committee").

(2) The Technical Committee shall comprise —

(a) the Permanent Secretary of the Federal Ministry of Health who shall be the Chairman;

(b) all Directors of the Federal Ministry of Health;

(c) the Legal Adviser of the Federal Ministry of Health;

(d) the Permanent secretaries and two Directors (one of whom shall be responsible for health services) of all State Ministries of Health and FCT Department responsible for Health;

(e) one representative each of the Armed Forces Medical Corps; that is, Army, Air Force and Navy;

(f) one representative of the Prisons Medical Services;

(g) one representative each of the parastatals of the Federal Ministry of Health;

(h) one representative each of all statutory health regulatory agencies or councils;

(i) the Chairman of the Committee of Chief Executives of Teaching and Specialist Hospitals and Federal Medical Centres;

(i) one representative each of the registered health professional associations including traditional medicine practitioners and alternative health care providers; and

(k) one representative of the private health care providers.

(3) The Federal Ministry of Health shall provide the Secretariat for the administrative activities of the Technical Committee.

- Functions of 7. (1) The Technical Committee shall advise the National Council on its functions as contained in Technical Committee. section 5(1) of this Act and any other matters that the council may refer to it.
- Conduct 8. (1) The Technical Committee shall strive to reach its decisions by consensus but where a Proceedings of the decision cannot be reached by consensus; the decision of the majority of the members shall Technical Committee. prevail and be regarded as the decision of the Technical Committee.

Establishment and Composition of the Technical Committee of the National Council.

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(2) The Technical Committee may create one or more ad hoc committees of experts in health matters to advise it on any matter with which it is concerned.

(3) The Technical Committee shall determine the proceedings for its meetings and the quorum for its meetings shall be not less than one third of its membership, including the person presiding at any such meeting.

9. (1) There is hereby established, a Committee to be known as the National Tertiary Health Institutions Standards Committee.

Establishment of the National Tertiary Health Institutions Standards Committee.

(2) The Committee shall consist of:

(a) the Chairman who shall be a person in the health profession with vast knowledge and experience in health service delivery, planning and organization to be appointed by the Minister.

- (b) Representative of the following :-
- (i) Ministry of Finance;
- (ii) Ministry of Education; and
- (iii) Office of the Head of Service of the Federation.
- (c) Representatives of Chief Executives of Tertiary Hospitals;
- (d) the Registrars of all health professions regulatory agencies or councils in Nigeria;

(e) six persons appointed on merit by the Minister, one from each geographical zone to represent the public interest at least two of whom shall be women;

(f) one person to represent the organized private sector; and

(g) the Director, Department of Hospital Services, Federal Ministry of Health .

(h) the Secretary of the Committee shall be a Health Care Service Professional who shall be appointed after a comprehensive examination conducted by the Committee.

(3) A member of the Committee other than an ex-officio member shall:-

(a) hold office for a term of four (4) years and no more, on such terms and conditions as may be specified in his letter of appointment;

(b) vacate his office if he resigns through a letter written under his hand .

(4)The Federal Ministry of Health shall provide the secretariat for the administrative activities of the Committee.

(5) The National Tertiary Health Institutions Standards Committee shall meet not less than four times in a year.

(6) The National Tertiary Health Institutions Standards Committee shall regulate its own procedure and the quorum shall be 2/3 majority.

10. (1) The functions of the Committee shall be to -

Functions of the Committee.

(a) advise the Minister on matters affecting the establishment of Tertiary Hospitals in Nigeria;

(b) Prepare periodic master plans for the balanced and coordinated development of tertiary hospitals in Nigeria;

(c) establish minimum standards to be attained by the various tertiary health facilities in the nation and also to inspect and accredit such facilities;

(d) make relevant investigations and recommendations to the Federal and State Governments on tertiary health care services in the national interest;

(e) advice the Federal Government on the financial needs, both recurrent and capital, of tertiary health services and in particular investigate and study the financial needs for training, research and services and make appropriate recommendations for these.

(f) set standards and criteria for allocation of funds from the Federal Government to Tertiary Health Institutions and monitor their utilization, source for grants as laid down by the committee

(g) collate, analyse and publish information in relation to tertiary health care services annually;

(h) lay down broad operational guidelines in all areas of management for use by the tertiary hospitals Management Board;

(i) monitor and evaluate all activities and receive annual reports from the tertiary hospitals and supervise annual peer reviews; and

(j) carry out such other activities as are conducive for the discharge of its functions under this Bill.

(2) The Minister may give the Committee directives of a general nature not relating to the particular matters with regard to the exercise by the Committee of its functions under this Bill but the Committee is not bound to accept or follow such directives.

11. (1) There is hereby created a Fund to be known as Basic Health Care Provision Fund.

Establishment of Basic Health Care Provision Fund.

(2) The Basic Health Care Provision Fund shall be financed from-

(a) Federal Government Annual Grant of not less than one per cent of its Consolidated

Revenue Fund.

(b) grants by international donor partners; and

(c) funds from any other source.

(3) Money from the fund shall be used to finance the following:-

(a) 50% of the fund shall be used for the provision of basic minimum package of health services to citizens, in eligible primary/or secondary health care facilities through the National Health Insurance Scheme (NHIS);

(b) 20 percent of the fund shall be used to provide essential drugs, vaccines and consumables for eligible primary health care facilities;

(c) 15 per cent of the fund shall be used for the provision and maintenance of facilities, laboratory, equipment and transport for eligible primary healthcare facilities; and

(d) 10 per cent of the fund shall be used for the development of Human Resources for Primary Health Care;

(e) 5 percent of the fund shall be used for Emergency Medical Treatment to be administered by a Committee appointed by the National Council on Health.

(4) the National Primary Health Care Development Agency shall disburse the funds for items 3(b)(c)(d) above through State and Federal Capital Territory Primary Health Care Boards for distribution to Local Government and Area Council Health Authorities.

(5) For any State or Local Government to qualify for a block grant pursuant to sub-section (1) of this section, such State or Local Government shall contribute –

(a) in the case of a State, not less than 25 per cent of the total cost of projects; and

(b) In the case of a Local government, not less than 25 per cent of the total cost of projects as their commitment in the execution of such projects.

(6) The National Primary Health Care Development Agency shall not disburse money to any-

(a) Local Government Health Authority if it is not satisfied that the money earlier disbursed was applied in accordance with the provisions of this Bill;

(b) State or Local Government that fails to contribute its counterpart funding and;

(c) States and local governments that fail to implement the national health policy, norms, standards and guidelines prescribed by the National Council on Health.

(7) The National Primary Health Care Development Agency shall develop appropriate guidelines for the administration, disbursement and monitoring of the fund with the

approval of the Minister in Council.

PART II - HEALTH ESTABLISHMENTS AND TECHNOLOGIES

12. (1) The Minister-in-Council shall by regulation – Classification of Health Establishment and Technologies.

(a) classify all health establishments and technologies into such categories as may be appropriate, based on:

(i) their role and function within the national health system;

(ii) the size and location of the communities they serve;

(iii) the nature and level of health services they are able to provide;

(iv) their geographical location and demographic reach;

(v) the need to structure the delivery of health services in accordance with national norms and standards within an integrated and coordinated national framework; and

(vi) in the case of private health establishments, whether the establishment is for profit or not; and

(b) in the case of federally owned tertiary hospitals, determine the establishment of the hospital board and the management system of such tertiary hospital.

(2) Nothing in the forgoing provision of this section shall preclude the House of Assembly of any State from making laws for that state for the regulation and inspection of public, private and non-governmental health facilities in that state.

Certificate 13. (1) Without being in possession of a Certificate of Standards, a person, entity, government or Standards. organization shall not :-

(a) establish, construct, modify or acquire a health establishment, health agency or health technology;

(b) increase the number of beds in, or acquire prescribed health technology at a health establishment or health agency;

(c) provide prescribed health services; or

(d) continue to operate a health establishment, health agency or health technology after the expiration of 24 months from the date this Bill took effect.

(2) The Certificate of Standards referred to in subsection (1) of this section may be obtained by application in prescribed manner from the appropriate body of government where the facility is located. In the case of tertiary institutions the appropriate authority shall be the National Tertiary Health Institutions Standards Committee, acting through the Federal Ministry of Health.

Offences and Penalties Any person, entity, government or organisation who performs any act stated under section 14.

of

respect 13(1) without a Certificate of Standards required by that section is guilty of an offence and in Certificate shall be liable on conviction to a fine of not less than N500,000.00 or in the case of an Standards. individual to imprisonment for a period not exceeding two years or both.

15. (1) The Minister, in respect of a tertiary hospital, and the Commissioner, in respect of all other public health establishments within the State in question, may:-

(a) Determine the range of health services that may be provided at the relevant public health establishments; and

(b) In consultation with the relevant Treasury, determine the proportion of revenue generated by a particular public health establishment classified as a hospital that may be retained by that hospital, and how those funds may be used.

(2) The minister, in consultation with the National Council may prescribe conditions subject to which categories of persons may be eligible for exemption from payment for health care services rendered by public health establishments.

(3) Without prejudice to any prescription made by the minister, in terms of subsection (2) of this section, all citizens shall be entitled to a basic minimum package of health services.

16. (1) The Minister in Council may prescribe:-

> (a) minimum standards and requirements for the provision of health services in locations other than health establishments, including schools and other public places; and

> (b) penalties for any contravention of or failure to comply with any such standards or requirements.

> (2) The Minister may, subject to the provisions of any other law, prescribe conditions relating to traditional health practices to ensure the health and well-being of persons who are subject to such health practices.

> (3) Without prejudice to the above the House of Assembly in any State may make laws for the provision of health services at non health establishments in the state.

17. (1) Subject to this Bill, a user may attend any health establishment for the purposes of receiving health services.

(2) If a health establishment is not capable of providing the necessary treatment or care, the health establishment in question shall refer the user concerned to an appropriate health establishment which is capable of providing the necessary treatment or care (in such manner or such terms as may be prescribed by regulation).

(1) The Minister shall prescribe mechanisms to ensure a co-ordinated relationship between 18. private and public health establishments in the delivery of health services.

(2) The Federal Ministry, any state ministry or any Local Government or any public health

Establishments and at Public Health Establishment other than Hospitals.

at

Health Services

Non-Health

Referral from one Health Establishment to another.

Relationship between Public and Private Health Establishments.

of of

health Provision of services at Public Health Establishments.

establishment may enter into an agreement with any private practitioner, private health establishment or non-governmental organization in order to achieve any objective of this Bill.

19. (1) All health establishments shall comply with the quality requirements and standards prescribed by the National Council on Health.

(2) The quality requirements and standards stated in subsection (1) may relate to human resources, health technology, equipment, hygiene, premises, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated.

(3) the National Tertiary Health Institutions Standards Committee shall monitor and enforce compliance with the quality requirements and standards stated in subsection(1) as it relates to Tertiary Hospitals.

PART III – RIGHTS AND OBLIGATIONS OF USERS AND HEALTHCARE PERSONNEL

20. (1) A health care provider, health worker or health establishment shall not refuse a person ^{Emergency treatment.} emergency medical treatment for any reason whatsoever.

(2) Any person who contravenes this section is guilty of an offence and is liable on conviction to a fine of N100, 000.00 (one hundred thousand naira) or to imprisonment for a period not exceeding six months or to both.

21. (1) Subject to any applicable law, the head of the health establishment concerned may in accordance with any guideline determined by the Minister, Commissioner or any other appropriate authority impose conditions on the services that may be rendered by a health care provider or health worker on the basis of health status except if the health personnel claims a conscientious exemption.

(2) Subject to any applicable law, every health establishment shall implement measures to minimise—

(a) injury or damage to the person and property of health care personnel working at that establishment; and

(b) disease transmission.

(3) Without prejudice to section 19(1) and except for Psychiatric patients, a health care provider may refuse to treat a user who is physically or verbally abusive or who sexually harasses him or her, and in such a case the health care provider should report the incident to the appropriate authority.

22. Subject to not being found negligent, a health care provider or other officers or employees of a health care establishment shall be indemnified out of the assets of the health care establishment against any liability incurred by him in defending any proceeding, whether civil or criminal in which judgement is given in his favour or is acquitted, if any such proceeding is brought against him in his capacity as a health care provider, an officer or employee of a health care establishment.

Indemnity of the HealthCare provider, Officer or Employee of a HealthCare Establishment. 23. (1) Every health care provider shall give a user relevant information pertaining to his state of health and necessary treatment relating thereto including:-

(a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;

(b) the range of diagnostic procedures and treatment options generally available to the user;

(c) the benefits, risks, costs and consequences generally associated with each option; and

(d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

(2) The health care provider concerned shall, where possible, inform the user in a language that the user understands and in a manner which takes into account the user's level of literacy.

- The Federal Ministry, every State Ministry of Health, every Local Government Health Authority 24. Information. and every private health care provider shall ensure that appropriate, adequate and comprehensive information is disseminated and displayed at facility level on the health services for which they are responsible, which shall include-
 - (a) the types of health services available;
 - (b) the organisation of health services;
 - (c) operating schedules and timetables of visits;
 - (d) procedures for laying complaints; and
 - (e) the rights and duties of users and health care providers.
- **Obligation to Keep** 25. Subject to applicable archiving legislation, the person in charge of a health establishment Record. shall ensure that a health record containing such information as may be prescribed is created and available at that health establishment for every user of health services.
- Confidentiality 26. (1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential.

(2) Subject to section 27, no person may disclose any information contemplated in subsection (1) unless-

- (a) the user consents to that disclosure in writing;
- (b) a court order or any law requires that disclosure; or
- (i) in the case of a minor with the request of a parent or guardian; and

(ii) in the case of a person who is otherwise unable to grant consent upon the request of a guardian or representative.

Duty to Disseminate

(c) non-disclosure of the information represents a serious threat to public health.

- 27. A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interest of the user.
- 28. (1) A health care provider may examine a user's health records for the purposes of:-

(a) treatment with the authorisation of the user; and

(b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.

(2) If the study, teaching or research under subsection (1)(b) of this section reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection.

Protection of Health (1) The person in charge of a health establishment who is in possession of a user's health 29. Records. records shall set up control measures to prevent unauthorised access to those records and to the storage facility in which, or system by which, records are kept.

(2) Any person who—

(a) fails to perform a duty imposed on them under subsection (1);

(b) falsifies any record by adding to or deleting or changing any information contained in that record;

(c) creates, changes or destroys a record without authority to do so;

(d) fails to create or change a record when properly required to do so;

(e) provides false information with the intent that it be included in a record;

(f) without authority, copies any part of a record;

(g) without authority, connects the personal identification elements of a user's record with any element of that record that concerns the user's condition, treatment or history;

(h) gains unauthorised access to a record or record-keeping system, including intercepting information being transmitted from one person, or one part of a record-keeping system, to another;

(i) without authority, connects any part of a computer or other electronic system on which records are kept to-

(i) any other computer or other electronic system; or

Access to Health Records.

Access to Health Records by Health Care Provider.

(ii) any terminal or other installation connected to or forming part of any other computer or other electronic system; or

(j) without authority, modifies or impairs the operation of—

(i) any part of the operating system of a computer or other electronic system on which a user's records are kept; or

(ii) any part of the programme used to record, store, retrieve or display information on a computer or other electronic system on which a user's records are kept:

commits an offence and is liable on conviction to imprisonment for a period not exceeding two years or to a fine of N250,000.00 or both.

30. (1) Any person may lay a complaint about the manner in which he or she was treated at a Laying of Complaints. health establishment and have the complaint investigated.

(2) The Minister, Commissioner or any other appropriate authority shall establish a procedure for the laying of complaints within the areas of the national health system for which the Federal or State Ministry is responsible.

(3) The procedures for laying complaints shall—

(a) be displayed by all health establishments in a manner that is visible for any person entering the establishment and the procedure shall be communicated to users on a regular basis;

(b) in the case of a private health establishment, allow for the laying of complaints with the head of the relevant establishment;

(c) include provisions for the acceptance and acknowledgment of every complaint directed to a health establishment, whether or not it falls within the jurisdiction or authority of that establishment; and

(d) allow for the referral of any complaint that is not within the jurisdiction or authority of the health establishment to the appropriate body or authority.

(4) In laying a complaint, the person stated in subsection (1) shall follow the procedure established by the Minister or a Commissioner, as the case may be.

PART IV - NATIONAL HEALTH RESEARCH AND INFORMATION SYSTEM

31. (1) There shall be established by the Minister, a National Health Research Committee (in this Bill referred to as "the Research Committee").

Establishment, Composition and Tenure of National Health Research Committee.

(2)(a) The membership of the Research Committee shall consist of not more than 13 members appointed by the Minister on the recommendation of the health research

institutions and other related bodies in the Federation.

(b) the membership of this research committee established in terms of this section shall reflect the federal character of Nigeria.

(3) There shall be for the committee -

(a) a Chairman who shall be an acknowledged health researcher and be accomplished and renowned in a health discipline.

(b) a secretary who shall be the Director of Health Planning and Research in the Federal Ministry of Health.

(4) A person appointed pursuant to subsection (2)(a) of this section shall -

(a) hold office for a term of three years in the first instance and may be re-appointed for another term of three years and no more, under such terms and conditions as may be specified in his letter of appointment; and

(b) vacate his office if he resigns through a letter written under his hand or in case of permanent incapacitation or death.

(5) The Research Committee shall have the responsibility to -

(a) promote health research to be carried out by public and private health authorities;

(b) ensure that health research agenda and research resources focus on priority health problems;

(c) develop and advise the Minister on the application and implementation of an integrated national strategy for health research; and

(d)collate and document information on the research activities of public and private health establishments.

(6) A member of the Research Committee who is not employed on full-time basis in the public service shall in respect of his service as member be paid such remuneration as may be determined by the Minister.

32. (1) Notwithstanding anything to the contrary in any other law, every research or experimentation on a living person shall only be conducted:-

Research or Experimentation with Human subject.

(a) in the manner prescribed by the relevant authority; and

(b) with the written consent of the person after he shall have been informed of the objects of the research or experimentation and any possible effect on his health.

(2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted -

(a) if it is in the best interest of the minor;

(b) in such manner and on such conditions as may be prescribed by the National Health Research Ethics Committee;

(c) with the informed written consent of the parent or guardian of the minor.

(3) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted –

(a) in such manner and on such conditions as may be prescribed by the National Health Research Ethics Committee; and

(b) with the informed written consent of the parent or guardian of the minor.

33. (1) There shall be established by the Minister, a National Health Research Ethics Committee (in this Bill referred to as "the National Ethics Committee").

(2) The membership of the Ethics Committee shall consist of not more than 15 persons which shall include -

- (a) a Chairman;
- (b) a medical doctor;
- (c) a legal practitioner;
- (d) a pharmacist;
- (e) a nurse;
- (f) a medical laboratory scientist,
- (g) a health record officer,
- (h) a radiographer,
- (i) physiotherapist,
- (j) one representative each of the Christian and Islamic faith;
- (k) a community health worker;
- (I) one researcher in the medical field;
- (m) one researcher in the pharmaceutical field;

Establishment, Composition, Function and Tenure of National Health Research Ethics Committee. (n) one researcher in medical laboratory science field; and

(o) three other persons at least one of whom shall be a woman who in the opinion of the Minister are of unquestionable integrity.

(3) A member of the Ethics Committee shall be appointed for a term of three years in the first instance and may be reappointed for another term of three years and no more under such terms and conditions as may be specified in his letter of appointment.

(4) A member of the Ethics Committee shall vacate his office if he resigns or is requested in the public interest by the Minister to do so.

(5) If a member of the Ethics Committee vacates his office or dies, the Minister may fill the vacancy by appointing a person in accordance with subsection (2) for the unexpired term of office of his predecessor.

(6) The National Ethics Committee shall have power to determine the guidelines to be followed for the functioning of Institutional health research ethics committees, and for the avoidance of any doubt shall-

(a) set norms and standards for conducting research on humans and animals, including clinical trials;

(b) determine the extent of health research to be carried out by public and private health authorities;

(c) adjudicate in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by any of the health research ethics committees;

(d) register and audit the activities of health research ethics Committees;

(e) refer to the relevant statutory health regulatory body, matters involving the violation or potential violation of an ethical or professional rule by a health care provider

(f) recommend to the appropriate regulatory body such disciplinary action as may be prescribed or permissible by law against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Bill; and

(g) advise the Federal Ministry of Health and State Ministries of Health on any ethical issues concerning research on health.

(7) For the purposes of subsection (6)(a), "clinical trials" means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of prevention and treatment.

(1) Every institution, health agency and health establishment at which health research is Establishment and 34. conducted, shall establish or have access to a health research ethics committee, which is

functions of Health **Research Ethics**

registered with the National Ethics Committee.

(2) A health research ethics committee shall:-

(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases;

(b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee; and

(c) perform other functions that may be referred to it by the Minister.

35. (1) The Federal Ministry of Health shall facilitate and co-ordinate the establishment, implementation and maintenance by State Ministries, Local Government Health Authorities and the private health sector of the health information systems at national, state and local government levels in order to create a comprehensive National Health Management Information System.

(2) The Minister may, for the purpose of creating, maintaining or adapting databases within the national health information system desired in subsection (1), of this section prescribe categories or kinds of data for submission and collection and the manner and format in which and by whom the data is to be compiled or collated and shall be submitted to the Federal Ministry of Health.

(3) The Minister and Commissioners shall publish annual reports on the state of health of the citizenry and the health system of Nigeria including the States thereof.

- 36. The Secretary responsible for Health shall by this Bill establish a Committee for the FCT to maintain, facilitate and implement the health information system under section 35(1) of this Bill, at FCT and Area Council levels.
- 37. Each Area Council, which provides health services shall establish and maintain a health information system as part of the national health information system as specified under section 35(1) of this Bill.
- 38. (1) All private health care providers shall:-

(a) establish and maintain a health information system as part of the national health information system as specified under section 35(1) of this Bill; and

(b) ensure compliance with the provision of sub-section (1)(a) as a condition necessary for the grant or renewal of the Certificate of Standards.

(2)Any private health care provider that neglects or fails to comply with the provision of subsection(1) of this section shall be guilty of an offence and on conviction shall be liable to imprisonment for a term of six months or a fine of N100,000 or both.

(3) Nothing in the foregoing precludes a State Assembly from making laws with regards to

Coordination of National Health Management Information System (NHMIS).

Duties of the FCT as regards Health Information.

Duties of FCT Area Councils.

Duties of Private HealthCare Providers. health information system for that State and the Local Government Areas and the private health sector within that State.

39. (1) There shall be a compendium of drugs approved for use in health facilities throughout the Federation- (in this Bill referred to as the "Essential Drugs List") which shall be under the periodic review of the National Drugs Formulary, and Essential Drugs List Review Committee.

(2) Indigenous and local manufacture and production of as many items in the formulary as practicable shall be encouraged.

40. It shall be the responsibility of the National Council on Health to ensure the widest possible catchments for the health insurance scheme throughout the federation or any part thereof.

PART V - HUMAN RESOURCES FOR HEALTH

41. (1) The National Council shall develop policy and guidelines for, and monitor the provision, distribution, development, management and utilisation of, human resources within the national health system.

(2) The policy and guidelines stated in subsection (1) shall amongst other things facilitate and advance—

(a) the adequate distribution of human resources;

(b) the provision of appropriately trained staff at all levels of the national health system to meet the population's health care needs; and

(c) the effective and efficient utilisation, functioning, management and support of human resources within the national health system.

- 42. The Minister, with the concurrence of the National Council shall determine guidelines that will enable the State Ministries and Local Governments to implement programmes for the appropriate distribution of health care providers and health workers.
- 43. The Minister shall make regulations with regard to human resources management within the national health system in order to:-

(a) ensure that adequate resources are available for the education and training of health care personnel to meet the human resources requirements of the national health system;

(b) ensure the education and training of health care personnel to meet the requirements of the national health system, including the prescription of a re-certification programme through a system of continuing professional development;

(c) create new categories of health care personnel to be educated or trained in conjunction with the appropriate authority;

(d) identify shortages of key skills, expertise and competence within the national health system, and prescribe strategies which are not in conflict with any other existing legislation,

National Drugs Formulary and Essential Drugs List and Safety of Drugs and Food Supply.

National Health Insurance Scheme.

Development and Provision of Human Resources in National Health System.

Appropriate Distribution of Health Care Providers.

Regulations Relating to management of Human Resources in the Health System. for the "education and training of health care providers or health workers in the Federation, to make up for any shortfall in respect of any skills; expertise and competences; and

(e) prescribe strategies for the recruitment and retention of health care personnel within the national health system and from anywhere outside Nigeria;

(f) ensure the existence of adequate structures for human resources planning, development and management at national, state and local government levels of the national health system in conjunction with the National Council on Health;

(g)ensure the availability of institutional capacity at state and local governments levels of the national health system to plan for, develop and manage human resources in conjunction with the National Council on Health;

(h) ensure the definition and clarification of the roles and functions of the Federal Ministry of Health, state ministries of health and local government health authorities with regard to the planning, production and management of human resources in conjunction with the National Council on Health; and

(i) prescribe circumstances under which health care personnel may be recruited from other countries to provide health services in the Federation.

- 44. The National Council shall ensure that there is adequate plan for manpower development Training Institutions. throughout the federation or any part thereof to keep pace with evolving trends of expansion and improvement in health care delivery.
- 45. (1) Without prejudice to the right of all cadres and all groups of Health Professionals to Industrial Dispute. demand for better conditions of service, health services shall be classified as Essential Service, and subject to the provisions of the relevant law.

(2) Pursuant to subsection (1) of this section, industrial disputes in the public sector of Health shall be treated seriously and shall on no account cause the total disruption of health services delivery in public institutions of health in the federation or in any part thereof.

(3) Where the disruption of health services has occurred in any sector of National Health System, the Minister shall apply all reasonable measures to ensure a return to normalcy of any such disruption within fourteen days of the occurrence thereof.

46. Without prejudice to the right of any Nigerian to seek medical check-up, investigation or treatment anywhere within and outside Nigeria no public officer of the government of the Federation or any part thereof shall be sponsored for medical check-up, investigation or treatment abroad at public expense except in exceptional cases on the recommendation and referral by the medical board and which recommendation or referral shall be dully approved by the Minister or the Commissioner of health of the state as the case may be.

PART VI - CONTROL OF USE OF BLOOD, BLOOD PRODUCTS, TISSUE AND GAMETES IN HUMANS

47. (1) The Minister shall establish a National Blood Transfusion Service for the Federation.

National Blood Transfusion Services.

(2) The Minister shall make regulations for the establishment and maintenance of the National Blood Transfusion Service.

(3) Without prejudice to the provision of sub-section(1) of this section, the States may set up Blood Transfusion Service as they find appropriate within their jurisdiction.

48. (1) Subject to the provision of section 53, a person shall not remove tissue, blood or blood product from the body of another living person for any purpose except;

(a) with the informed consent of the person from whom the tissue, blood or blood product is removed granted in prescribed manner;

(b) that the consent clause may be waived for medical investigations and treatment in emergency cases; and

(c) an accordance with prescribed protocols by the appropriate authority.

(2) A person shall not remove tissue which is not replaceable by natural processes from a person younger than eighteen years.

(3) A tissue, blood or a blood product shall not be removed from the body of another living persons for purpose of merchandise, sale, or commercial purposes.

(4) A person who contravenes the provisions of this section or fails to comply therewith is guilty of an offence and liable on conviction as follows:

(a) in the case of tissue, a fine of N1,000,000 or imprisonment of not less than two years or both; and

(b) in the case of blood or blood products, a fine of N100,000 or imprisonment for a term not exceeding one year or both.

49. (1) Subject to the provision of section 52, a person shall use tissue removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribe.

(2) "a person who contravenes the provisions of this section or fails to comply therewith is guilty of an offence and liable on conviction as follows":-

(a) in the case of tissue, a fine of N1,000,000 or imprisonment of not less than two years or both.

(b) in the case of blood or blood products, a fine of N100,000 or imprisonment for a term not exceeding one year or both.

50. (1) A person shall not:-

Prohibition of Reproductive and Therapeutic Cloning of

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Removal of Tissue, Blood or Blood Products from Living persons.

Use of Tissue, Blood or Blood Products removed or withdrawn from living persons. (a) manipulate any genetic material, including genetic material of human gametes, zygotes ^{Human Kind.} or embryos; or

(b) engage in any activity including nuclear transfer or embryo splitting for the purpose of the cloning of human being.

(c) import or export human zygotes or embryos.

(2) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to imprisonment for a minimum of five years with no option of fine.

51. (1) A person shall not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except:-

(a) in a hospital authorised for that purpose; and

(b) on the written authority of:

(i) the medical practitioner in charge of clinical services in that hospital or any other medical practitioner authorised by him or her; or

(ii) in the case where there is no medical practitioner in charge of the clinical services at that hospital a medical practitioner authorised thereto by the person in charge of the hospital.

(2) The medical practitioner stated in subsection (1)(b) shall not be the lead participant in a transplant for which he has granted authorisation under that subsection.

(3) For the purpose of transplantation, there shall be an independent tissue transplantation Committee within any health establishment that engages in the act and practice of transplantation as prescribed.

52. (1) Only a registered medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes stated in this Bill or transplant tissue so removed into another living person.

(2) Only a registered medical practitioner or dentist, or a person acting under the supervision or on the instructions of a medical practitioner or dentist, may administer blood or a blood product to, or prescribe blood or a blood product for, a living person.

53. (1) It is an offence for a person:-

(a) who has donated tissue, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and

(b) to sell or trade in tissue, blood, blood products except for reasonable payments made in appropriate health establishment for the procurement of tissues, blood or blood products

Removal, Use or Transplantation of Tissue and Administering of Blood and Blood Products by Medical Practitioner or Dentist.

Payment in Connection with the Importation, Acquisition or Supply of Tissue, Blood or Blood Product.

Removal and Transplantation of Human Tissue in Hospital. (2) Any person found guilty of an offence under subsection (1) is liable on conviction to a fine of N100,000 (one hundred thousand naira) or to imprisonment for a period not exceeding one year or to both.

54. (1) Human organs obtained from deceased persons for the purpose of transplantation or treatment, or medical or dental training or research, shall only be used in the prescribed manner.

Allocation and Use of Human Organs.

- (2) Human organs obtained under subsection (1) shall be allocated as prescribed.
- (3) The National Tertiary Health Institutions Standards Committee shall prescribe: -
- (a) criteria for the approval of organ transplant facilities; and
- (b) procedural measures to be applied for such approval.

(4) A person who contravenes a provision of this section or fails to comply therewith or who charges a fee for a human organ is guilty of an offence and shall be liable to imprisonment for a minimum of five years without option of fine.

55. (a) A person who is competent to make a will may:-

(i) in the will; or

(ii) in a document signed by him and at least two competent witnesses; or

(iii) in a written statement made in the presence of at least two competent witnesses, donate his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose provided for in this Bill.

(b) A person who makes a donation as stated in paragraph (a) above may nominate an institution or a person as donee.

- 56. (1) A donation under section 55 may only be made for the purposes of:-
 - (a) training of students in health sciences;
 - (b) health research;
 - (c) advancement of health sciences;
 - (d) therapy including the use of tissue in any living person; or

(e) production of a therapeutic, diagnostic or prophylactic substance.

(2) This Bill does not apply to the preparation of the body of a deceased person for the purposes of embalming it, whether or not such preparation involves the:-

Donation of Human Bodies and Tissue of Deceased Persons.

Purposes of Donation of Body, Tissue etc.

(a) making of incisions in the body for the withdrawal of blood and the replacement thereof by a preservative; or

(b) restoration of any disfigurement or mutilation of the body before its burial.

- Procedure for A donor may, prior to the removal for transplantation of the relevant organ into the donee, 57. Revocation of any revoke a donation in the same way in which it was made or, in the case of a donation by way Donation. of a will or other document, also by the intentional revocation of that will or codicil or document.
- 58. (1) Subject to subsection (2), a post mortem examination of the body of a deceased person Examination of Bodies. may be conducted if-

Post Mortem

(a) the person, while alive, gave consent thereto;

(b) the spouse, child, parent, guardian, brother or sister of the deceased not below the age of eighteen (18) years in the specific order mentioned, gave consent thereto; or

- (c) such an examination is necessary for determining the cause of death.
- (2) A post mortem examination may not take place unless-

(a) the medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, has authorised the post mortem examination in writing and in the prescribed manner; or

(b) In the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorized by the person in charge of such hospital or authorized institution, has authorized the post mortem examination in writing and in the prescribed manner.

PART VII – REGULATIONS AND MISCELLANEOUS PROVISIONS

- Regulations. 59. The Minister, in consultation with the National Council, may make regulations with regard to any other matter which is reasonably necessary or expedient to prescribe in the implementation of this Bill.
- Powers of Minister to 60. (1) The Minister may, after consultation with the National Council, establish such number of appoint Committees. advisory and technical committees as may be necessary to achieve the objects of this Bill.

(2) When establishing an advisory or technical committee, the Minister may determine by notice or circular:-

- (a) its composition, functions and working procedure; and
- (b) any incidental matters relating to that advisory or technical committee.

61. (1) The Minister shall establish a body to be known as the National Consultative Health Forum.

(2) The National Consultative Health Forum shall promote and facilitate interaction, communication and the sharing of information on National Health issues between representatives of the Federal Ministry of Health, National Organisations identified by the Minister and State organisations.

- 62. (1) The Minister may assign any duty and delegate any power imposed or conferred upon him by this Bill, except the power to make regulations to:
 - (a) any person in the employment of the Federal Government; or
 - (b) any council, board or committee established in terms of this Bill.

(2) A Commissioner may assign any duty and delegate any power imposed or conferred upon him or her by this Bill, except the power to make regulations to any officer in the relevant State Ministry or any Council, Board or Committee established in terms of this Bill.

(3) The Permanent Secretary of the Federal Ministry may assign any duty and delegate any power imposed or conferred upon him or her by this Bill to any official in the Federal Ministry of Health.

(4) The Permanent Secretary of a State Ministry may assign any duty and delegate any power imposed or conferred upon him or her in terms of this Bill to any official.

63. (1) Anything done before the commencement of this Bill under a provision of any other relevant Act or regulation which could have been done under a provision of this Bill shall be regarded as having been done under the corresponding provision of this Bill.
Savings and transitional provisions.

(2) The Minister may prescribe such further transitional arrangements as may be necessary in the circumstance.

64. In this Bill, unless the context otherwise requires:-

"appropriate authority" means any other authority apart from the Minister, Commissioner, Executive Secretary, Chairmen of Boards or Chairman of Agency;

"basic minimum package" means the set of health services as may be prescribed from time to time by the Minister after consultation with the National Council on Health;

"blood product" means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;

"certificate of standards" means a certificate under section 13;

"Commissioner" means the Commissioner of a State responsible for health;

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Interpretation.

Assignment of Duties and delegation of powers.

National Consultative Health Forum. "communicable disease" means a disease resulting from an infection due to pathogenic agents or toxins generated by the infection, following the direct or indirect transmission of the agents from the source to the host;

"Constitution" means the Constitution of the Federal Republic of Nigeria, 1999;

"death" means brain death;

"embryo" means a human offspring in the first eight weeks from conception;

"Federal Ministry" means the Federal Ministry of Health;

"gamete" means either of the two generative cells essential for human reproduction; "gonad" means a human testis or human ovary;

"health agency" means any person/or entity other than a health establishment:-

(a) whose business involves the supply of health care personnel to users or health establishments;

(b) who employs health care personnel for the purpose of providing health services; or

(c) who procures health care personnel or health services for the benefit of a user, and includes a temporary employment service involving health workers or health care providers;

"health care personnel" means health care providers and health workers;

"health care provider" means a person providing health services under Act of Law;

"health establishment" means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health service under section 12;

"health research" includes any research which contributes to knowledge of:-

(a) the biological, clinical, psychological or social processes in human beings;

(b) improved methods for the provision of health services;

(c) human pathology;

(d) the causes of disease;

(e) the effects of the environment on the human body;

(f) the development or new application of pharmaceuticals, medicines and related substances; and

(g) the development of new applications of health technology;

"health research ethics committee" means any committee established under section 34;

"health services" means health care services that are preventive, protective, promotive, curative and rehabilitative in respect of physical mental and social well being;

"health technology" means machinery or equipment that is used in the provision of health services, but does not include medicine as defined in the Drugs and Related Products Registration etc Act. No. 19 of 1993;

"health worker" means any person who is involved in the provision of health services to a user, but does not include a health care provider;

"hospital" means a health establishment which is classified as a hospital by the Minister under section 12;

"Minister" means the Minister charged with responsibility for matters relating to health;

"National Council on Health" means the Council established by section 4:

"national health policy" means all policies relating to issues of national health as approved by the Federal Executive Council on the advice of the National Council on Health through the Minister;

"National Health Research Committee" means the Committee established under section 31;

"National Health Research Ethics Committee" means the Committee established under section 33;

"National health system" means the system within the Federal Republic of Nigeria, whether in the public or private sector, concerned with the financing, provision or delivery and regulation of health services;

"non-communicable disease" means a disease or health condition that cannot be contracted from another person, an animal or directly from the environment;

"norm" means a statistical normative rate of provision or measurable target outcome over a specified period of time;

"NPHCDA" means the National Primary Health Care Development Agency;

"Office of Standards Compliance" means the Office established under this Bill;

"oocyte" means a developing human egg cell;

"organ" means any part of the human body adapted by its structure to perform any

particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete;

"Permanent Secretary" means the administrative head of the Federal Ministry of Health or a State Ministry of Health;

"premises" means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance or ship;

"prescribed" means prescribed by regulation made under section 59;

"primary health care services" means such health services as may be prescribed by the Minister to be primary health care services;

"private health establishment "means a health establishment that is not owned or controlled by an organ of state;

"public health establishment" means a health establishment that is owned or controlled by a government body;

"reasonable cause" means any extenuating circumstance that prevents the healthcare provider, health worker or health establishment from providing emergency medical treatment to a person;

"rehabilitation" means a goal-orientated and time-limited process aimed at enabling impaired persons to reach an optimum mental, physical or social functional level;

"reproductive cloning of a human being" means the manipulation of genetic material in order to achieve the cloning of a human being and includes nuclear transfer or embryo splitting for such purpose;

"State Ministry" means any State Ministry responsible for health;

"Statutory Health Professional Council" means a professional regulatory body established by an Act or Law,

"Technical Committee" means the committee under section 6;

"Tertiary hospital" means a public or private hospital approved by the National Tertiary Hospital Committee to provide health services at a tertiary specialist level of care;

'therapeutic cloning'' means the manipulation of genetic material from adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues;

"this Bill" includes any regulation made thereunder;

"tissue" means human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete;

"use", in relation to tissue, includes preserve or dissect;

"user" means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is—

(a) below the majority age, "user" includes the person's parent or guardian or another person authorised by law to act on the first mentioned person's behalf; or incapable of taking decisions, "user" includes the person's spouse or, in the

(b) absence of such spouse, the person's parent, grandparent, adult child, brother, sister, or another

(c) person authorised by law to act on the first mentioned person's behalf; and

"zygote" means the product of the union of a male and a female gamete.

65. This Bill may be cited as the National Health Bill, 2014.

Short Title.

EXPLANATORY MEMORANDUM

The Bill seeks to provide a framework for the development and management of a health system within the Federal Republic of Nigeria.