EXPLANATORY MEMORANDUM

This Bill seeks to establish the National Health Facility Regulatory Agency of Nigeria (NHFRA) to regulate health services, empower health services users and support healthcare workers, through care standards setting, monitoring to ensure compliance with standards and accreditation for care quality and safety assurance.

ARRANGEMENT OF SECTIONS

Clause-

PART VI - STANDARDS FOR HEALTH SERVICE PROVIDERS

PART VII: MANAGEMENT, INSPECTION AND NON-COMPLIANCE

PART VIII: MISCELLANEOUS PROVISIONS

A BILL

For

AN ACT TO ESTABLISH THE NATIONAL HEALTH FACILITY REGULATORY AGENCY OF NIGERIA (NHFRA) TO REGULATE HEALTHCARE QUALITY THROUGH: SETTING OF HEALTHCARE STANDARDS, MONITORING COMPLIANCE TO STANDARDS, INVESTIGATIONS OF BREACHES OF STANDARDS AND ACCREDITATION OF HEALTH SERVICES PROVISIONS AND PROVIDERS AND FOR RELATED MATTERS.

Sponsor:

[ ] Commencement

ENACTED by the National Assembly of the Federal Republic of Nigeria:

PART 1: ESTABLISHMENT OF THE NATIONAL HEALTH FACILITY REGULATORY AGENCY OF NIGERIA (NHFRA) AND THE GOVERNING BOARD.

Establishment of the Agency.

1(1) There is established an Agency to be known as the National Health Facility Regulatory Agency (NHFRA) of Nigeria (in this Bill referred to as "the Agency").

(2) The Agency:

(a) shall be a body corporate with perpetual succession and a common seal and may sue and be sued in its corporate name; and

(b) may acquire, hold, mortgage, purchase and deal with property, whether movable or immovable.

Objectives of the Agency.

(3) In performing its functions and exercising its powers, the primary objective of the Agency shall be to set up necessary standards for primary and secondary healthcare in both public and private hospitals

and other health institutions, improve the quality and efficiency of health care services to the patients by setting adequate standards and ensure strict compliance with same.

2(1) There is established for the management of the affairs of the Agency a Governing Board (in this Bill referred to as "the Board").

Establishment and Constitution of Governing Board of the Agency.

(2) The Board shall consist of

(a) a Chairman;

(b) Director General of the agency/chief executive officer created in Clause 10 (1) of this Bill;

(c) a representative of the following Ministries, institutions and establishments:

(i) Federal Ministry of Health;

(ii) Registrars of Health Regulatory Bodies;

(iii) Federal Ministry of Finance;

(iv) Federal Ministry of Justice;

(v) Nigerian Medical Association

(vi) Medical and Dental Council of Nigeria;

(vii) Nursing and Midwifery Council of Nigeria;

(viii) Healthcare Providers Association of Nigeria (HCPAN);

(ix) Medical Laboratory Science Council of Nigeria (MLSCN);

(x) National Agency for Food and Drug Administration and Control

(xi) Pharmacy Council of Nigeria ;

(xii) Federal Competition and Consumer Protection Commission (FCCPC) of Nigeria.

(3) The members of the Board shall be appointed by the President, on the recommendation of the Minister.

(4) The Board chair may nominate a member to act in his/her absence from among the members (one member may perform this role for a maximum of 2 meetings in any two-year period), the member acting on behalf of the chair shall exercise the powers and duties of the chairman, and if the chairman has not nominated any, members present at a meeting shall nominate a person from their own ranks to preside at that meeting.

(5) A member (including chair) of the Board shall -

(a) be a person of unquestionable character and proven integrity - a person with no criminal records, who has not been previously banned or sanctioned by a regulatory body.

(b) The chair shall be a medically qualified professional with a wealth of experience in clinical standards management.

(6) The Board shall meet for the conduct of its ordinary meetings at least 4 times in a calendar year.

(7) Notwithstanding the provision of sub clause (6) of this clause, the Board may meet to conduct such other business as exigency demands.

(8) The supplementary provision set out in the schedule to this Bill shall have effect with respect to the proceeding of the Board and other related matters.

3 The Board shall, subject to the provisions of this Bill, have powers to- Powers of the Board.

(a) manage and superintend the affairs of the Agency;

(b) advise the Federal Government generally on the national policies on the standards, control and supervision of health facilities;

(c) designate, establish and approve quality specifications and standards in respect of healthcare facilities, necessary for their accreditation;

(d) establish and approve the relevant guidelines and measures for quality control of healthcare facilities in conformity with the Agency's standards;

(e) appoint, promote and discipline employees necessary for the proper discharge of the functions of the Agency;

(f) establish committees as may be expedient which shall be charged with specific functions delegated by the Board;

(g) utilise and promote the expansion of research, surveys and studies by public or private agencies, institutions and organisations concerning the quality, safety and standards of health facilities and such other matters related to this Act as the Agency may, from time to time, determine as necessary or useful;

(h) establish, encourage and promote training programmes for the employees of the Agency and other appropriate persons from public or private organisations who shall act as accredited inspectors;

(i) formulate general policies for the regulation and development of the Agency;

(j) make and ensure enforcement of regulations relating to patient safety and care quality assurance;

(k) determine appropriate charges for penalty fees (for the following year);

(l) charge, retain and utilize for its purposes, costs or penalties imposed for violation of this Bill and subsidiary legislation enacted thereto;

(m) use all legal and appropriate means of enforcement to recover all costs or penalties imposed on any person for the purpose of administration of this Bill;

(n) make; alter, and revoke rules and regulations for carrying out the functions of the Agency; borrow money or dispose of any property (subject to the approval of the Board) as it deems fit;

(o) appoint either on transfer, secondment or leave of absence from any public service of the federation or private sector, such number of employees as may, in the opinion of the Board be required to assist the Agency in the discharge of any of its functions under this Bill;

(p) access information, for purpose of the discharge of its regulatory and supervisory duties in relation to health service providers, from any director, manager and officer, examine whenever necessary under conditions of confidentiality, books and affairs of such persons or corporate body subject to its regulation;

(q) delegate, by general or special order in writing, to any member or officer of the Agency or any other person subject to such conditions, if any, as may be specified in the order, such of its powers and functions under this Bill as it may deem necessary;

(r) determine the terms and conditions of service including remunerations of employees;

(s) make staff regulations relating generally to the conditions of service of employees of the Agency and without prejudice to the generality of the foregoing, such regulations may provide for:

(t) the appointment, promotion and disciplinary control including dismissal of employee of the Agency;

(u) Procedure for appeals by such employees against dismissal or other disciplinary measures; and

(v) Do such other things which in the opinion of the Board are necessary and expedient to ensure the efficient discharge of the functions of the Agency.

4(1) A member of the Board shall hold office for a term of four years renewable only once for another term of four years (and no more.)

Tenure of office of members of Board.

(2) No person shall be appointed as a member of the Board if he or she:

(a) is an undischarged bankrupt;

(b) fails to comply or is not capable of fully complying with a judgment or order, including an order for costs, given against him or her by a court of law in a civil case;

(c) in the preceding 10 years has been convicted of an offence of which fraud, violence, dishonesty, extortion or intimidation, medical negligence or other forms of mal-practice is an element; or

(d) is not a citizen of the Federal Republic of Nigeria.

5(1) A member of the Board shall vacate his or her office if he or she-

Cessation of Membership.

(a) Upon appointment becomes guilty of any of infringement in clause 4 above;

(b) becomes of unsound mind;

(c) is absent without the leave of the secretary for more than three consecutive meetings of the Board.

6 There shall be paid to every member of the Board such allowances as the Agency may from time to time determine.

Allowances of Members of Board.

PART II: FUNCTIONS OF THE AGENCY.

7 The Agency shall:

Functions of the Agency.

a) set standards for primary and secondary healthcare;
b) inspect and accredit health facilities listed in a Schedule to this Act;
c) inspect primary and secondary healthcare facilities where one or more licensed professionals offer services to the public to ensure safety;
d) accredit all (primary and secondary health services in private and public ownership) through; inspections, monitoring, accreditation and enforcement activities;
e) support the state ministries of health to develop the required capacity to provide effective oversight;
f) set licensing standards to support state government, and audit this function to ensure uniformity of standards across the states of the Federation;
g) set required minimum standards for operations of health facilities both in public and private health sectors as shown in the Schedule to this Act;
h) collate all necessary information on registered health facilities in the Federation;
i) advise the Minister for Health on all matters relating to the accreditation, inspection and supervision of primary and secondary care in private and public hospitals in the Federation;
j) execute the functions conferred on it by or under any enactment;
k) train healthcare inspectors or surveyors for its inspections;
l) review the performance of all health services providers and award an annual performance rating to each organization;
m) appoint franchise companies to monitor, inspect and ensure compliance with this law by all health facilities in the federation;
n) publish healthcare outcomes in open domain;
o) investigate breaches of the provisions of this Bill;
p) receive, investigate and manage patients' complaints about health services not resolved by the providers where they touch on standards;
q) publish 'Never events' list in consultation with health professionals and providers and review the list annually;
r) create awareness on patient safety and care quality incidents and publish lessons to be learnt;

s) monitor the safe use of medical devices for healthcare to ensure that safe standards are adhered to;
t) safeguard patients and purchasers from abuses of electronic medical records (EMR);
u) establish committees or specialized departments for the purpose of effective regulation and discharge of the Agency's functions under the Bill;
v) accept gifts of land, money or other testamentary dispositions, endowments and contributions on such terms and conditions, if any, as may be specified by the donor of the gift (provided that the Agency shall not accept any gift if the conditions attached thereto by the donor are inconsistent with the functions of the Agency);
w) conduct routine and special inspection which may be announced or unannounced and investigation of health service providers;
x) promote partnerships with national and international organizations; and
y) perform such other functions as may be determined by the Board to give effect to the provisions of this Bill.

8 (1) The Agency shall encourage compliance with the provisions of this Bill, by- Other Functions of the Agency

(a) monitoring all primary and secondary care facilities where healthcare may be offered to the public;
(b) collecting and publishing of performance ratings;
(c) ensuring that all health service providers follow the duty of candour process;
(d) Keeping, updating and publishing a database to hold names of health service professionals and providers who are in breach of provisions of this Act.

9 The Agency shall have the powers to- Powers of the Agency

a. receive applications for accreditation of premises for health facility;

b. inspect primary and secondary healthcare facilities where one or more licensed professional offer healthcare services to the public;

c. supervise private health facilities registered under this Act;

d. supervise public health facilities under this Act;

e. issue certificate of standards in respect of any premises to be licensed (by the relevant state government);

f. issue certificate of accreditation in respect of any premises registered under this Act;

g. charge fees payable for application forms and for any other services rendered under this Act;

h. suspend, revoke or cancel any certificate of accreditation issued under this Act;

i. set up standards for primary and secondary healthcare facilities;

j. monitor strict compliance with the set standards;

k. enforce compliance for the improvement of health services to patients; and

l. acquire public and private sector resources to achieve the set objectives.

PART III: STRUCTURE OF THE AGENCY

10(1) For the purposes of effective administration, the Agency shall be structured into 8 operational departments and 4 directorates, as follows- Structure of the Agency.

(a) Safety and Quality Department
(b) Health Infrastructure (Engineering/Inspectorate) Department
(c) Risk, Enforcement and Compliance Department
(d) Standards, Certification and Accreditation Department
(e) Finance and Account Department

(f) Legal Services Department
(g) Servicom/Public Relations Department
(h) Procurement Department
(i) Operations Directorate
(j) Corporate Services Directorate
(k) Health Planning, Research and Statistics Directorate
(l) Information and Communication Technology

(2) The Board may create additional directorate, departments, inspectorates and Committees based on management recommendation and prevailing circumstances.

(3) Each Directorate shall be headed by a Director [or acting director] who is charged with the responsibility of coordinating the functions of such department and reporting to the Chief executive officer/Director General as spelt out by the Board (in the Administrative manual of the Agency).

(4) The Agency shall have zonal and state level offices

PART IV: STAFF OF THE AGENCY: DIRECTOR GENERAL (CHIEF EXECUTIVE OFFICER) AND OTHER STAFF OF THE AGENCY

Office of the Director General.

11(1) There is established for the Agency, a Director General, who shall be the Chief executive officer.

(2) The Director General shall be responsible for establishing and monitoring patient safety and care quality standards for all in Nigeria, and the general administration of the Agency.

(3) The Director General shall be the Chief Executive and Accounting Officer of the Agency and a member of the Board of the Agency. He/she shall be appointed by the President subject to confirmation by the Senate;

(4) The Office of the Director General, shall be responsible for the preparation, publication and three to four yearly review of patient charter detailing rights and responsibilities of every patient, healthcare worker and healthcare provider.

(6) The Director General shall be a medical practitioner of over twenty-five years, and a specialist in care quality standards management of over ten years, with proven experience and integrity.

(7) The Director General shall hold office for a term of four years renewable only once for another term of four years, (and no more).

(8) The Director General shall be responsible for the day to day administration of the Agency, keeping the books and proper records of the proceedings of the Board, and the administration of the secretariat of the Board.

(9) The Director-General shall cause an up to date register to be kept and maintained containing details of all public and registered health facilities under the Agency and such other particulars as the Minister may prescribe.

(10) The Director-General shall secure the safety of the register which shall be in his custody.

(11) No person may insert, delete, alter or cause to be altered any material particular in the register relating to any registered health facility unless the Agency so directs such alteration, deletion or insertion in writing.

12(1) A Franchise Company shall be a limited liability company with wide experience in health care facilities establishment and management including quality assurance.

Conditions for appointing a Franchise Company

(2) A Franchise Company shall have a registered office within the state or region(s) it has been appointed to operate and staff complement to include all categories of health workers and shall be assisted by staff of the Local Government and State Government as the case may be.

(3) An appointed Franchise Company shall carry out the monitoring and inspection of public and private health facilities in the State.

13(1) The Board shall appoint for the Agency such number of employees as may in the opinion of the Board be expedient and necessary for the proper and efficient performance of the functions of the Agency. Other staff of the Agency

(2) The terms and conditions of service (including remuneration, allowances, benefits and pensions) of the employees of the Agency shall be as determined by the Board.

PART V: FINANCIAL PROVISIONS

14(1) There shall be established and maintained by the Agency, a Fund into which shall be paid and credited- Fund of the Agency.

(a) all allocations from the Federal Government;

(b) such monies as may, from time to time, be lent, deposited or granted to the Agency by the Government of the Federation or of a State;

(c) all Grants received from both local and international organizations for the purpose of the Agency;

(d) fees, levies, penalties, charges, administrative costs of proceedings, licensing fees, accreditation fees, training fees and other monies payable to the Agency in pursuance of this Bill;

(e) all monies received by the Agency as gifts, loans, contributions, testamentary deposition or donations; and

(f) 5 percent of the Basic Health Care Provision Fund, which is meant for development of human resources in order to ensure quality healthcare services and improved health outcomes.

(g) all other monies and assets which may accrue to the Fund from time to time.

(2) The Fund shall be managed in accordance with rules made by the Board and without prejudice to the generality of the power to make rules under this sub clause, the rules shall in particular contain provisions-

(a) Specifying the manner in which the assets of the Fund are to be held and regulating the making payments into and out of the Fund; and

(b) Requiring the keeping of proper accounts and records for the purposes of the Fund in such form as may be specified in the rules.

15 The Agency shall apply the proceeds of the Fund established pursuant to Section 13 of this Bill to- Expenditure of the Agency.

(i) cost of administration of the Agency;
(ii) payment of salaries, fees, remuneration, bills, rent;
(iii) cost of maintenance of any property acquired or vested in the Agency;
(iv) capital expenditure approved by the Agency;
(v) allowances, salaries, remuneration, pensions and gratuities payable to the members of the Board specified in clause 5 of this Bill or any Committee of the Board and the employees of the Agency, so however that no payment of any kind under this paragraph (except such as may be expressly authorized by the Board) shall be made to any person who is in receipt of emolument from the government of the Federation or a State;
(vi) the payment for all contracts, including mobilization, fluctuations, variations, legal fees and cost on contract administration;
(vii) the payment for all purchases; and
(viii) undertaking such other expenses and activities as are connected with all or any of the functions of the Agency under this Bill.

16(1) The Agency may accept gifts of land, money or other property on such terms and conditions considered lawful. Gifts to the Agency.

(2) The Agency shall not accept any gift if the conditions attached by the person or organization making the gift are inconsistent with the functions of the Agency under this Bill.

17 The Agency may, with the approval of the Board, borrow, on such terms and conditions as the Agency may require in the exercise of its functions under this Bill. Power to borrow.

18(1) The Director General shall, not later than 30th September of each year, submit to the Board, an estimate of the expenditure and income for the next succeeding year. Annual Estimates and Expenditure.

(2) The Board shall cause to be kept proper accounts of the Agency in respect of each year and proper records in relation thereto and shall cause the accounts to be audited not later than 6 months after the end of each year by auditors appointed from the list in accordance with the guidelines supplied by the Auditor-General of the Federation.

19 The Board shall prepare and submit to the Minister, not later than 30th June in each year, a report in such form as the President may direct on the activities of the Agency during the immediately preceding year, and shall include in the report a copy of the audited accounts of the Agency for that year and auditor's report thereon. Annual Report.

PART VI – STANDARDS FOR SAFE HEALTH SERVICE PROVISION BY PROVIDERS

20 To ensure Healthcare provisions are qualitative and safe, every Healthcare Provider shall- Standards for Health Service Providers

(a) adhere to fundamental standards of care that are established by professional bodies and endorsed by the Agency;
(b) Where professional bodies and or fundamental standards are lacking (absolute) or lacking in quality, the Agency shall with the support of professionals in that field set the required standards of care;
(c) be subjected to monitoring, accreditation and re-accreditation through periodic inspections (announced and unannounced) by the Agency;
(d) continuously improve quality of care provided;
(e) publish its ratings from the Agency in open domain (in forms available and accessible to patients) and
(f) ensure the availability of structures and systems essential for the delivery of qualitative and safe care in compliance with provisions of this Bill.

(2) A Health service provider that causes moderate harm or above (severe harm, Never Event or death directly related to a harm caused to a patient in care, shall be required to follow the duty of candour process:

(a) explain the harm to the patient or the patient's next of kin within 72 hours of the harm being discovered;
(b) write a letter/correspondence explaining the incident within 10 days of the incident being discovered;
(c) initiate an investigation on the incident within 2 weeks, involve the patient or family or career in the investigation process, and
(d) report findings within 6 weeks to relevant stakeholders including the patient or the patient's family.

(3) Every Health service Provider shall
(a) refund any fee or cost of treatment paid by a patient who is harmed in the process of receiving any treatment; and
(b) bear the cost of any corrective or further treatments resulting from the harm inflicted on the patient.

Accreditation of Health Facilities and issuance of Certificate of Standards

21(1) As from the commencement of this Act, no person shall establish, carry on or run health facility in any premises without accreditation/registration by the relevant state government body or agency, in the state the health facility is located, and accredited by the Agency with a corresponding certificate of standards.

(2) The Agency shall have the powers to issue additional grades of accreditation to signify higher healthcare standards set out in the Guidelines in the Schedules to this Act.

Appeal to the Minister against the Agency's decision

22(a) Any person aggrieved by the decision of the Agency in accordance with the provisions of this Act may appeal in writing to the Minister against such decision

(b) Such appeal shall:

(w) Be lodged within 60 days from the date on which written reasons for the decision were given by the Agency or such later date as the Minister permits; and

(ii) Set out the grounds of the appeal

(c) After considering the grounds of the appeal and the Agency's reasons for the decision, the Minister shall as soon as practicable –

(i) Confirm, set aside, or vary the decision
(ii) substitute any other decision for the decision of the Agency

Certificate of Standards

23(1) The Agency shall issue a Certificate of Standards to any facility that applies under this Act and has satisfied the conditions in this Act, in respect of premises to be used for a health facility.

(2) A Certificate of Standards shall also operate as confirmation of achievement of stage 1 accreditation by such health facility.

(3) Every health facility licensed by a state government and accredited by the Agency shall be required to engage with the Aency's accreditation process at least once in every three years.

Renewal

(4) A certificate of standards shall be deemed to have expired if no accreditation progress has been made since three years from the achievement of the last accreditation grade, this shall automatically trigger a fall to the previous accreditation grade, which would be due for renewal.

(5) Where a healthcare facility has failed to make any accreditation progress beyond the certificate of standards/licensing (stage 1) in three years, such a facility shall be required to undergo re-certification (stage 1) standards assessments to ensure that it still meets the minimum standards to legally operate.

Sanctions

(6) Where a facility with expired certificate of standards fails to engage or fails the re-certification standards assessments, the certificate of standards shall be withdrawn by the Agency, this withdrawal shall automatically trigger the state government entity or agency in charge of such state certification to commence withdrawal of the state issued certificate of standards or operating license.

24 A Certificate of Standards issued by the Agency shall be signed by the Director-General and shall contain the Seal of the Agency.

25 The Agency shall investigate and apply sanctions to any defaulting health facility for non-provision of specified healthcare records and statistics in respect of standards or for non-compliance with set standards.

26 The following certificates shall be displayed in a conspicuous place in any health facility: Display of Certificates

(a) Certificate of Standards issued by the Agency;

(b) Current License to practice issued by the relevant body of a State Government that is in charge of registration of health facilities;

(c) Certificate of Accreditation issued by the Agency; and

(d) Professional Certificate of the head of the Facility

27(1) The Director General shall prepare and maintain, in accordance with rules made by the Agency under this clause, a register of accredited health services providers - the names, addresses, and approved qualifications and of such other particulars as may be specified of organisations, who qualify as heath care providers under this Bill. Preparation and maintenance of register

(2) Subject to the provisions of this clause, the Agency shall make rules with respect to the form of keeping of the register and the making of entries therein.

PART VII – MANAGEMENT, INSPECTION AND COMPLIANCE

28 Subject to the provisions of this Act –

(a) every health facility shall be under the management, control and supervision of a Medical Practitioner referred to in this Act as the Medical Practitioner in-Charge or the Responsible Officer; Management of Health Facility.

(b) every laboratory or diagnostic centre shall be under the management, control and supervision of other suitably qualified personnel who shall be responsible (Responsible Officer) for carrying into effect the provisions of this Act or any other Act in the health facility concerned.

29 Subject to the provisions of this Law, the Minister may give to the Agency, general or specific direction as to what fees to charge for the initial accreditation and re-accreditations of health facilities and the Agency shall comply and give effect to these directives.

Power of the Minister to regulate Fees.

30(1) The Agency or its duly authorised officers may enter premises in respect of which the Agency had received application for accreditation for the purpose of inspection and to ensure that conditions for certificate of standards and subsequent accreditations are being complied with.

Inspection and Supervision

(2) The Agency or its duly authorized agent, or its duly authorised Franchisees/Franchise Companies may enter (announced and unannounced) any registered health facility in any State for the purpose of inspection and to ensure that conditions for registration under this Act are being complied with.

Provided that nothing in this section shall be deemed to authorise the inspection of any medical record relating to a particular patient in a health facility.

(3) The Agency or its duly authorized officers, or Franchise Companies shall inspect every health facility at least once every three years to ensure compliance with this Act but may conduct announced or unannounced inspections of health facility at any time.

Notice of non-compliance

31(1) The Agency shall issue a written notice of non-compliance to the head of the health facility if the Agency determines that the health facility does not comply with:

i. Any provision of this Act;

ii. Set standards flowing from this Act as determined by the Agency;

iii. provisions of any other law

(2) A notice of non-compliance shall be issued to the person responsible for any condition contemplated in subsection (1) above stating the nature and extent of the non-compliance and directing the appropriate corrective action to be

taken within a specified period in respect of the health service practice or to minimize or rectify compliance.

(3) A notice of non-compliance contemplated in subsection (2) above remains in force until the relevant provisions of this Act have been complied with and the Agency has issued a compliance correspondence/certificate showing that the issues have been resolved, in respect of the notice.

(4) A notice of non-compliance contemplated in subsection (2) shall also be served on the responsible State government agency where defaulting health facility is located, for additional supervision and monitoring.

Power to cancel certificate of standards and withdraw accreditation

32 Where it appears to the Agency that the provisions of this Law are not being carried into effect in a health facility or that the health facility is not being conducted in the best interest of the health or well-being of the patients admitted thereto or that any medical practitioner connected with the health facility has ceased to be fit and proper person, the Agency may by order:

(a) suspend the subsistence of the certificate of standards/accreditation issued to such health facility until the conditions which caused the order of suspension to be issued have been rectified; or
(b) cancel the certificate of standards or accreditation of such health facility if the conditions that warranted the suspension is not rectified within six (6) months:

Power of temporary closure

33(1) The withdrawal of certificate of standards by the Agency shall automatically trigger the responsible state government agency or body to commence withdrawal of operational license and temporary closure procedures against the facility.

(2) The Agency and the applicable State government agency or body for health facility registration, shall jointly enforce a temporary closure of a health facility if— (a) the health facility has not been duly registered with the Agency; or (b) the health facility is being run by unqualified personnel or persons not registered with the appropriate professional body.

(3) When an order of suspension, temporary closure by the withdrawal of operational license by the responsible state government agency has been triggered, the needs of in-patients shall be considered, and such health facilities shall thereupon be closed and the in-patients shall, in the discretion of the Agency and the responsible state government agency, be discharged or

transferred to another hospital or retained in the said health facility which has been so closed until they are fit to be discharged or transferred and such retention of in-patients shall not be deemed to constitute an offence under the provisions of this Law. The cost incurred in effecting such transfer shall be borne by the offending health facility.

34 Any person aggrieved by a suspension, temporary closure or cancellation made under the provisions of this Section may appeal to the Minister.

Appeal to the Minister

35 Any order of suspension, temporary closure or cancellation made under the provisions of this Section shall be in addition to any proceedings which may be instituted in respect of any contravention or failure to comply with the provisions of this Act and to any penalties which may be imposed on conviction in such proceedings whether or not such conviction is heard on the facts on which the order of suspension, temporary closure or cancellation was made.

Order of suspension, temporary closure or cancellation to be in addition to other sanctions

Provided that no such order of suspension or cancellation of registration shall be made until the medical practitioner in charge of such health facility has had an opportunity of defending himself either personally or in writing before the Agency.

36 Any person who willfully delays or obstructs a person duly authorized by the Agency in the performance of its functions under this Law, or fails without reasonable excuse to give any information, which he is duly required to give shall be guilty of an offence and shall be liable to a fine as specified in this Act.

Obstruction of duly authorized person from the Agency.

PART IX: MISCELLANEOUS PROVISIONS

37(1) A person aggrieved by any action or decision of the Agency under this Bill, including such action or decision taken on the basis of the Agency's power under this Bill may bring an action in the Court provided that the aggrieved person shall give the Agency 30 days' notice in writing of his intention to bring an action against such action or decision.

Pre action notice

(2) The intending Plaintiff shall serve on the Agency a formal written notice which shall clearly and explicitly state-

(a) the cause of action;
(b) the particulars of the claim;
(c) the name and place of abode of the intending plaintiff; and
(d) the reliefs which the Plaintiff intends to claim.

(3) The notice of intention to initiate an action against the Agency referred to in sub clauses (1) and (2) of this clause may be addressed to and delivered to the Director General.

38(1) Any health service provider that provides any service with an expired certificate of standards, shall be cautioned and subject to a sanction of ₦500, 000.00 or such other penalty as determined in the Operational Guidelines and Regulations. Penalties

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(2) Any health service provider that operates without accreditation or certificate of standards to a sanction of six month suspension by the Agency, or such other sanction as determined in the Operational Guidelines and Regulations.

(3) Any health service provider that fails to provide information or documents with regard to harm inflicted on a patient shall be subject to a lowest grade rating, suspension of license for six months by the Agency, publication of such activity in the national news and print media and sanction of N1,000,000.00, and such other penalty as determined in the Operational Guidelines and Regulations to this Bill.

(4) Any health service provider that fails to abide by the "Duty of Candour" policy when a patient is harmed, shall be cautioned, and given two weeks to comply with the process and shall be liable to such sanctions as determined by the Operational Guidelines and Regulations made pursuant to this Bill.

(5) Any heath service provider that contravenes any regulation or policy made pursuant to this bill shall be subject to sanctions, which would include, withdrawal or suspension of its license, publication of such activity in the national news and print media, and such other sanctions as determined in the Operational Guidelines and Regulations made pursuant to this Bill.

(7)
(a) Any person who obstructs an official of the Agency from entry for inspection, shall on conviction be liable to a fine of ₦1,000, 000.00 or to a term of imprisonment not exceeding six months or both; and
(b) the health service provider shall be subjected to a six month suspension and to sanctions as to cover the cost of subsequent visits for inspection

as determined by the Operational Guidelines and Regulations made pursuant to this Bill.

(8) Any person who destroys or conceals evidence of harm inflicted on a patient, or coerces another person to do so, shall on conviction be liable to a fine of ₦2,000, 000.00 or to a term of imprisonment not exceeding two years or both.

(9) The Agency may in addition to any penalty that may be prescribed under this Act, issue directions and sanctions to any person who has contravened any of the provisions of this Bill and any regulation made there under, to compensate any person who may have suffered any direct loss or injury as a result of the contravention.

(10) Notwithstanding the provisions of subsections (2), of this section the complainant of a contravention may seek by action, consequential or punitive damages or any other remedy that may be available under the law after exploring the remedies provided by the Agency.

(12) Any person who conceals or destroys evidence of history of criminal records, bankruptcy, sanctions by regulatory agencies in order to gain employment into the Agency, shall on conviction be liable to a fine determined by the Agency Board and a term of imprisonment not exceeding six months or both.

(13) In the exercise of its powers to impose a penalty under this Bill, the Agency shall accord the person in the alleged violation a fair hearing.

(14) Notwithstanding anything contained in any other provision or the sections under this Act, the Agency shall at all times retain the power to sanction erring Health Service Provider or any Health Facility in line with the operational guidelines and Regulations made pursuant to this Bill.

39 The Minister may give directives of a general nature or relating generally to matters of policy with regard to functions of the Agency and it shall be the duty of the Agency to comply with the directives.

Directives by the Minister, etc.

40 The Director General may make regulations and operational guidelines as may be necessary or expedient for giving full effect to the provisions of this Bill and for its administration thereof.

Powers of the Director General to make Regulations.

41(1) For the purposes of providing offices and premises necessary for the performance of its functions under this Bill, the Agency may, subject to the Land Use Act- Offices and Premises of the Agency.

(a) purchase or take on lease any interest land, or other property; and

(b) Construct offices and premises and equip and maintain same.

(2) The Agency may, subject to the Land Use Act, sell or lease out any office or premises held by it, which office or premises is no longer required for the performance of its functions under this Bill.

42(1) Subject to the provisions of this Bill, the provisions of the Public Officers Protection Act shall apply in relation to any suit against any member or Officer or employee of the Agency. Limitation of suits against the Agency.

(2) Notwithstanding anything contained in any other law or enactment, no suit shall lie against any member of the Board, the chairman or any other officer or employee of the Agency for anything done in pursuance or execution of this Bill or any other law or enactment, or any alleged neglect or default in the execution of this Bill or such law or enactment, duty or authority, shall lie or be held against the Agency in any court unless-

(a) it is commenced within three months after the act, neglect or default complained of; or

(b) in the case of a continuation of damage or injury, within six months after the leasing thereof.

43 A notice, summons or other document required or authorized to be served upon the Agency under the provisions of this Bill or any other law or enactment may be served by delivering it to the Director General. Service of document.

44 In any action or suit against the Agency, no execution or attachment of process shall be made against the Agency, unless not less than three months' notice of the intention to execute or attach has been given to the Agency. Restriction of execution against property of the Agency.

45 In this Bill unless the context otherwise requires- Interpretation

"Agency" means the National Health Facility Regulatory Agency (NHFRA) of ;

"Board" means the Governing Board of the Agency;

"Clinical governance" means a systematic approach to maintaining and improving the quality of patient care within a health system,

including education/training, clinical audits and clinical risk management;

"Clinical Audit) means a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards and the implementation of change;

"Duty of candour" means a duty on health service providers to be open and honest with patients when something that goes wrong with their treatment or care causes or has the potential to cause, harm or distress.

The health service provider must -

(i) tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong;

(ii) apologise to the patient (or, where appropriate, the patient's advocate, carer or family);

(iii) offer an appropriate remedy or support to put matters right (if possible), and

(iv) explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short and long term effects of what has happened.

"Health facility" means any premises, or part of a private or public institution, building or place, whether for profit or not, that is designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative, or other health service where one or more licensed health care professional(s) offer the said health care services to the public.

"Health service providers" means clinics, medical centres, private health institutions, public health institutions, hospitals, diagnostic and treatment centres, mobile clinics, laboratories, etc;

"Low Harm" means incidents that lead to further minor treatments (more observations) e.g. uncomplicated fall of a patient in hospital;

"member" means a member of the Board and includes the Chairman;

"Moderate harm" means incidents that result in additional moderately increased treatments or prolonged stay in hospital e.g. return to surgery to correct complication of first surgery, unplanned admission to intensive care unit (ICU) or significant but not permanent harm;

"Minister" means the Minister for Health, Federal Republic of Nigeria;

"Never Events" *means* serious incidents that are preventable had measures been implemented by health service providers e.g. removal of wrong organ or limb, wrong prosthesis or implant (wrong lens placed during cataract surgery}, wrong route administration of drugs (giving drugs meant for oral route as injection or IV drug given into the spine), operating on a wrong patient;

"Premises" means any building, structure or tent together with the l and 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;

"Patient Safety" means a framework of organized activities that create cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur." (WHO, 2021);

"President" means the President of the Federal Republic of Nigeria;

"Severe Harm" means incident that result in permanent harm such as removal of wrong organ, paralysis or brain damage, and

"Director General" means the chief executive officer of the Agency responsible for maintenance of health services safety and quality standards and the administration and management of the Agency.

46 This Bill may be cited as National Health Facility Regulatory Agency of Nigeria, 2025. Citation.

SCHEDULE **Clause 2 (8)**

SUPPLEMENTARY PROVISIONS RELATING TO THE BOARD

Proceedings of the Governing Board.

1(1) Subject to this Bill and section 24 of the Interpretation Act, the Board may make standing orders regulating its proceedings or those of any of its committees.

(2) The quorum of the Board shall be half of the total number of members. The quorum of any committee of the Board shall be determined by the Board.

2(1) The Board shall meet not less than 4 times in each year and subject thereto, the Board shall meet whenever it is summoned by the Chairman, and if the Chairman is required to do so by notice given to him by not less than half of the Board membership, he shall summon a meeting of the Board to be held within 14 days from the date on which the notice is given.

(2) At any meeting of the Board, the Chairman shall preside but if he is absent, the members present at the meeting shall appoint one of them to preside at that meeting.

(3) Where the Board desires to obtain the advice of any person on a particular matter, the Board may co-opt him to the Board for such period as it thinks fit; but a person who is in attendance by virtue of this sub-paragraph shall not be entitled to vote at any meeting of the Board and shall not count towards a quorum.

Committees.

3(1) The Board may constitute one or more Committees to carry out, on behalf of the Board, such of its functions or the functions of the Commission as the Board may determine.

(2) A committee constituted under this paragraph shall consist of such number of persons (not necessarily members of the Board) as may be determined by the Board; and a person other than a member of the Board shall hold office on the committee in accordance with the terms of his appointment.

(3) Subject to the provisions of this Bill and the decision of the Board, a committee constituted under this Bill may regulate its own proceedings and business.

(4) A decision of a committee of the Board shall be of no effect until it is confirmed by the Board.

Miscellaneous.

4(1) The fixing of the seal of the Agency shall be authenticated by the signature of the Chairman and any other person authorized generally or specially to act for that purpose by the Board.

(2) Any contract or instrument which, if made or executed by a person not being a body corporate, would not be required to be under seal may be made or executed on behalf of the Agency by the Director General or any person generally or specially authorized to act for that purpose by the Board.

(3) Any document purporting to be a document duly executed under the seal of the Agency shall be received in evidence and shall, unless and until the contrary is proved, be presumed to be so executed.

5 The validity of any proceeding of the Board or of a committee thereof shall not be adversely affected by any vacancy in the membership of the Board or committee, or by any defect in the appointment of a member of the Board or of a committee, or by reason that a person not entitled to do so took part in the proceedings of the Board or committee.