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PATIENT SAFETY AGENCY OF NIGERIA (ESTABLISHMENT) BILL, 2018

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A BILL

FOR

AN ACT TO ESTABLISH THE PATIENT SAFETY AGENCY OF NIGERIA AS INDEPENDENT BODY TO REGULATE PATIENT SAFETY THROUGH HEALTH SERVICE QUALITY ASSURANCE: LICENSING, MONITORING, INVESTIGATIONS AND AUDITING OF HEALTH SERVICES PROVISIONS AND PROVIDERS AND FOR RELATED MATTERS

Sponsored by Hon. Yakubu Dogara

[] Commencement

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

1 PART 1 - ESTABLISHMENT OF THE PATIENT SAFETY AGENCY OF
2 NIGERIA AND THE GOVERNING BOARD.

3 1.-(1) There is established an Agency to be known as the Patient
4 Safety Agency of Nigeria (in this Bill referred to as "the Agency"). Establishment
of the Agency

5 (2) The Agency:

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

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

10 2.-(1) There is established for the management of the affairs of the
11 Agency a Governing Board (in this Bill referred to as "the Board"). Establishment
and Constitution
of Governing
Board of the
Agency

12 (2) The Board shall consist of:

13 (a) a Chairman;

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

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

18 (i) Federal Ministry of Health;

- 1 (ii) Public Health Services of Nigeria - Federal or state or academia;
2 (iii) Federal Ministry of Finance;
3 (iv) Federal Ministry of Justice;
4 (v) Nigerian Medical Association;
5 (vi) Medical and Dental Council of Nigeria;
6 (vii) Nursing and Midwifery Council of Nigeria;
7 (viii) Healthcare Providers Association of Nigeria;
8 (ix) Association of Medical Laboratory Scientists of Nigeria;
9 (x) NAFDAC;
10 (xi) Pharmaceutical Society of Nigeria;
11 (xii) Consumer Protection Council of Nigeria; and
12 (xiii) Standards Organisation of Nigeria (SON)
- 13 (3) The members of the Board shall be appointed by the President.
- 14 (4) The Board chair may nominate a member to act in his/her absence
15 from among the members (one member may perform this role for a maximum
16 of 2 meetings in any two-year period), the member acting on behalf of the chair
17 shall exercise the powers and duties of the chairman, and if the chairman has
18 not nominated any, members present at a meeting shall nominate a person from
19 their own ranks to preside at that meeting.
- 20 (5) A member of the Board shall-
- 21 (a) be a person of unquestionable character and proven integrity; and
22 (b) as much as possible reflect equitable representation from the six
23 geopolitical zones in Nigeria.
- 24 (6) The Board shall meet for the conduct of its ordinary meetings at
25 least 4 times in a calendar year.
- 26 (7) Notwithstanding the provision of sub clause (6) of this clause, the
27 Board may meet to conduct such other business as exigency demands.
- 28 (8) The supplementary provision set out in the schedule to this Bill
29 shall have effect with respect to the proceeding of the Board and other related
30 matters.

- 1 3. The Board shall, subject to the provisions of this Bill, have Powers of the
2 powers to- Board
- 3 (a) manage and superintend the affairs of the Agency;
- 4 (b) provide a systematic approach to maintaining and improving
5 the quality of patient care through training, clinical audits and clinical risk
6 management;
- 7 (c) formulate general policies for the regulation and development
8 of the Agency;
- 9 (d) make and ensure enforcement of regulations relating to patient
10 safety and management;
- 11 (e) charge, retain and utilize for its purposes, costs or penalties
12 imposed for violation of this Bill and subsidiary legislation enacted thereto;
- 13 (f) use all legal and appropriate means of enforcement to recover
14 all costs or penalties imposed on any person for the purpose of
15 administration of this Bill;
- 16 (g) make; alter, and revoke rules and regulations for carrying out
17 the functions of the Agency;
- 18 (h) borrow money or dispose of any property (subject to the
19 approval of the Board) as it deems fit;
- 20 (i) appoint either on transfer, secondment or leave of absence from
21 any public service of the federation or private sector, such number of
22 employees as may, in the opinion of the Board be required to assist the
23 Agency in the discharge of any of its functions under this Bill;
- 24 (j) access information, for purpose of the discharge of its
25 regulatory and supervisory duties in relation to health service providers,
26 from any director, manager and officer, examine whenever necessary under
27 conditions of confidentiality, books and affairs of such persons or corporate
28 body subject to its regulation;
- 29 (k) delegate, by general or special order in writing, to any member
30 or officer of the Agency or any other person subject to such conditions, if

1 any, as may be specified in the order, such of its powers and functions under this
2 Bill as it may deem necessary;

3 (l) determine the terms and conditions of service including
4 remunerations of employees;

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

8 (i) the appointment, promotion and disciplinary control including
9 dismissal of employee of the Agency; and

10 (ii) Procedure for appeals by such employees against dismissal or
11 other disciplinary measures.

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

Tenure of office
of members of
Board

15 **4.-(1)** A member of the Board shall hold office for a term of four years
16 renewable only once for another term of four years (and no more.)

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

19 (a) is an undischarged bankrupt;

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

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

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

Cessation of
Membership

27 **5.-(1)** A member of the Board shall vacate his or her office if he or she-

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

30 (b) becomes of unsound mind;

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

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

5 PART II - FUNCTIONS OF THE AGENCY

6 7. The Agency shall: Functions of the
Agency

7 (a) Develop and implement national policy for patient safety;

8 (b) Improve knowledge and learning in patient safety,

9 (c) Assess the safety and quality of healthcare and public health
10 services;

11 (d) Regulate all health licensing; inspections, activities;

12 (e) Review the performance of all health services providers and
13 award an annual performance rating to each organization;

14 (f) Publish healthcare outcomes;

15 (g) Publish information about the state of healthcare in Nigeria;

16 (h) Investigate breaches of the provisions of this Bill;

17 (i) Independently review patients' complaints about health services
18 not resolved by the providers;

19 (j) Promote the coordination of medical emergency alerts, reviews
20 and assessments carried out by other organizations, nationally and
21 internationally for the purpose of safeguarding patients in Nigeria;

22 (k) Publish 'Never events' list in consultation with health
23 professionals and providers and review the list annually;

24 (l) create awareness on patient safety incidents and publish lessons
25 to be learnt;

26 (m) Defend patients' rights including the right to humane treatment
27 and freedom from abuse such as freedom from neglect for example neglect
28 brought on by illegal strikes;

29 (n) Receive and manage patients' complaints;

30 (o) Investigate patient safety incidents;

- 1 (p) Minimize and control spread of healthcare-associated infection;
2 (q) Ensure safe health-care waste management;
3 (r) Promote appropriate use, quality and safety of medicines for
4 patients in partnership with NAFDAC;
5 (s) Provide training and support for Continuous Quality Improvement
6 for Health care professionals;
7 (t) establish committees or specialized departments for the purpose of
8 effective regulation and discharge of the Agency's functions under the Bill;
9 (u) accept gifts of land, money or other testamentary dispositions,
10 endowments and contributions on such terms and conditions, if any, as may be
11 specified by the donor of the gift (provided that the Agency shall not accept any
12 gift if the conditions attached thereto by the donor are inconsistent with the
13 functions of the Agency);
14 (v) conduct routine and special inspection and investigation of health
15 service providers;
16 (w) promote partnerships with national and international
17 organizations; and
18 (x) perform such other functions as may be determined by the Board
19 to give effect to the provisions of this Bill.
- 20 **8.** The Agency shall encourage compliance with the provisions of
21 this Bill, by-
- 22 (a) conducting training programmes on patient safety for health
23 service providers;
24 (b) granting Clinical Excellence Awards (CEA) to health care
25 professionals for delivering improved care In their organizations;
26 (c) providing for and publishing of performance ratings for service
27 provisions by health service providers - a stares) rating system;
28 (d) ensuring that all health service providers abide by the "Duty of
29 Candour" policy;
30 (e) Keeping, updating and publishing a database to hold names of

Other Functions
of the Agency

1 health service professionals and providers who neglect, abuse or collude
2 with or entice or coerce others to abuse patients.

3 PART III - STRUCTURE OF THE AGENCY

4 9.-(1) For the purposes of effective administration, the Agency
5 shall be structured into six operational departments in addition to
6 Administration and Finance as follows-

Structure of the
Agency

- 7 (a) Licensing;
8 (b) Training and Support;
9 (c) Monitoring;
10 (d) Investigations;
11 (e) Research & IT; and
12 (f) Health Watch.

13 (2) The Board may create additional departments and Committees
14 based on management recommendation and prevailing circumstances.

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

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

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

23 10.-(1) There is established for the Agency, a Director General,
24 who shall be the Chief executive officer.

Office of the
Director-General

25 (2) The Director General shall be responsible for establishing and
26 maintaining patient safety standards for all Nigerians, and the general
27 administration of the Patient Safety Agency of Nigeria.

28 (3) The Surgeon General shall be the Chief Executive and
29 Accounting Officer of the Agency and a member of the Board of the Agency.

1 He/she shall be appointed by the President subject to confirmation by the
2 Senate.

3 (4) The Office of the Director General, Nigeria shall be responsible
4 for the preparation, publication and three to four yearly review of Patient
5 Charter (National Healthcare Constitution) Rights and responsibilities of
6 every patient, healthcare worker and healthcare provider in Nigeria.

7 (5) The Director General shall prepare and publish annual State of
8 Health of the Nation report including a formal oral presentation which shall
9 allow for questions and answers session.

10 (6) To ensure the Director General has the right knowledge, skills and
11 experience to deal with matters - national and international, the post holder
12 shall be-

13 (a) a medical practitioner of not less than (25) years;

14 (b) A specialist of no less than 20 years' experience;

15 (c) At least 8 years in health leadership position;

16 (d) At least 3 years of (c) above would involve experience at national
17 and international healthcare quality and safety leadership level;

18 (e) a fit and proper person, with suitable skills and experience in
19 Health care quality management and Patient safety; and

20 (f) of proven integrity and ability.

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

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

Other staff of
the Agency

27 **11.**-(1) The Board shall appoint for the Agency such number of
28 employees as may in the opinion of the Board be expedient and necessary for
29 the proper and efficient performance of the functions of the Agency.

30 (2) The terms and conditions of service (including remuneration,

1 allowances, benefits and pensions) of the employees of the Agency shall be
2 as determined by the Board.

3 PART V - FINANCIAL PROVISIONS

4 **12.**-(1) There shall be established and maintained by the Agency, a Fund of the
5 Fund into which shall be paid and credited- Agency

6 (a) all allocations from the Federal Government;

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

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

11 (d) fees, levies, penalties, charges, administrative costs of
12 proceedings, and other moneys payable to the Agency in pursuance of this
13 Bill;

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

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

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

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

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

25 **13.** The Agency shall apply the proceeds of the Fund established
26 pursuant to clause 12 of this Bill to- Expenditure of
the Agency

27 (i) cost of administration of the Agency;

28 (ii) payment of salaries, fees, remuneration, bills, rent;

29 (iii) cost of maintenance of any property acquired or vested in the
30 Agency;

	1	(iv) capital expenditure approved by the Agency;
	2	(v) allowances, salaries, remuneration, pensions and gratuities
	3	payable to the members of the Board specified in clause 5 of this Bill or any
	4	Committee of the Board and the employees of the Agency, so however that no
	5	payment of any kind under this paragraph (except such as may be expressly
	6	authorized by the Board) shall be made to any person who is in receipt of
	7	emolument from the government of the Federation or a State;
	8	(vi) the payment for all contracts, including mobilization,
	9	fluctuations, variations, legal fees and cost on contract administration; (vii) the
	10	payment for all purchases; and
	11	(viii) undertaking such other expenses and activities as are connected
	12	with all or any of the functions of the Agency under this Bill.
Gifts to the Agency	13	14. -(1) The Agency may accept gifts of land, money or other property
	14	on such terms and conditions considered lawful.
	15	(2) The Agency shall not accept any gift if the conditions attached by
	16	the person or organization making the gift are inconsistent with the functions of
	17	the Agency under this Bill.
Power to borrow	18	15. The Agency may, with the approval of the Board, borrow, on such
	19	terms and conditions as the Agency may require in the exercise of its functions
	20	under this Bill.
Annual Estimates and Expenditure	21	16. -(1) The Director General shall, not later than 30th September of
	22	each year, submit to the Board, an estimate of the expenditure and income for
	23	the next succeeding year.
	24	(2) The Board shall cause to be kept proper accounts of the Agency in
	25	respect of each year and proper records in relation thereto and shall cause the
	26	accounts to be audited not later than 6 months after the end of each year by
	27	auditors appointed from the list in accordance with the guidelines supplied by
	28	the Auditor-General of the Federation.
Annual Report	29	17. -(1) The Board shall prepare and submit to the President, not later
	30	than 30th June in each year, a report in such form as the President may direct on

1 the activities of the Agency during the immediately preceding year, and shall
2 include in the report a copy of the audited accounts of the Agency for that
3 year and auditor's report thereon.

4 (2) The President shall, upon receipt of the report referred to in sub
5 clause (1) of this clause, cause a copy of the report and the audited accounts
6 of the Agency and the auditor's report thereon to be submitted to each House
7 of the National Assembly.

8 PART VI - STANDARDS FOR SAFE HEALTH SERVICE PROVISION

9 BY PROVIDERS

10 **18.** To ensure Healthcare provisions are qualitative and safe, every
11 Healthcare Provider shall-

Standards for
Health Service
Providers

12 (a) adhere to fundamental standards of care that are established by
13 professional bodies and endorsed by the Patient Safety Agency of Nigeria;

14 (b) Where professional bodies and or fundamental standards are
15 lacking (absolute) or lacking in quality, the Patient Safety Agency of Nigeria
16 shall with the support of professionals in that field (with current practical
17 experience) set the required standards of care;

18 (c) be subjected to monitoring, licensing and periodic inspections
19 (announced and unannounced) by the Agency;

20 (d) continuously improve quality of care provided;

21 (e) publish its ratings from the Agency in open domain (in forms
22 available and accessible to patients); and

23 (f) ensure the availability of structures and systems essential for the
24 delivery of qualitative and safe care in compliance with provisions of this
25 Bill.

26 (2) A Health service provider that causes moderate harm or above
27 (severe harm, Never Event or death directly related to a harm caused to a
28 patient in care, shall:

29 (a) be required to explain the harm to the patient or the patient's
30 next of kin within 72 hours of the harm being discovered;

1 (b) write an apology letter within 10 days of the incident being
2 discovered;

3 (c) initiate an investigation on the incident within 2 weeks, involve the
4 patient or family or caregiver in the investigation process, and

5 (d) report findings within 6 weeks to relevant stakeholders including
6 the patient or the patient's family.

7 (3) Every Health service Provider shall:

8 (a) refund any fee or cost of treatment paid by a patient who is harmed
9 in the process of receiving any treatment; and

10 (b) bear the cost of any corrective or further treatments resulting from
11 the harm inflicted on the patient.

12 (4) Patients may utilize documents, proceedings or reports from any
13 investigations initiated or conducted by a health service provider as evidence in
14 court proceedings.

Operations of
Sole health service
providers

15 **19.**-(1) Sole health service providers may provide non-emergency
16 services only as emergency services provision shall require the provider to be
17 continuously open for service for 24 hours of everyday.

18 (2) Sole health service providers who wish to provide emergency
19 services may partner with other sole health providers to pool manpower and
20 resources for emergency care (PolyClinic) or employ more staff to reach a
21 threshold of at least two doctors.

Preparation and
maintenance of
register

22 **20.**-(1) The Director General shall prepare and maintain, in
23 accordance with rules made by the Agency under this clause, a register of
24 accredited health services providers - the names, addresses, and approved
25 qualifications and of such other particulars as may be specified of
26 organisations, who qualify as safe health care providers under this Bill.

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

1 PART VII - MISCELLANEOUS PROVISIONS

2 **21.**-(1) A person aggrieved by any action or decision of the Agency Pre-action notice
3 under this Bill, including such action or decision taken on the basis of the
4 Agency's power under this Bill may bring an action in the Federal High
5 Court provided that the aggrieved person shall give the Agency 21 days'
6 notice in writing of his intention to bring an action against such action or
7 decision.

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

10 (a) the cause of action;

11 (b) the particulars of the claim;

12 (c) the name and place of abode of the intending plaintiff; and

13 (d) the reliefs which the Plaintiff intends to claim.

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

17 (4) The provision of this clause is not applicable to any decision of
18 the Disciplinary Committee as provided under this Bill which an aggrieved
19 person intends to appeal against.

20 **22.**-(1) Any health service provider that provides any service with Penalties
21 an expired license, shall be cautioned and subject to a fine of N100, 000.00.

22 (2) Any health service provider that operates without a license,
23 shall be subject to a six month suspension, publication of such activity in the
24 national news and print media and pay a fine of N1,000, 000.00.

25 (3) Any health service provider that fails to provide information or
26 documents with regard to harm inflicted on a patient shall be subject to a
27 lowest grade rating, suspension of license for six months, publication of
28 such activity in the national news and print media and a fine of
29 N1,000,000.00.

30 (4) Any health service provider that renders any service with a

1 suspended license, shall be subject to an additional one month added to the
2 suspension, publication of such activity in the national news and print media
3 and pay a fine pay a fine of N1,000,000.00.

4 (5) Any health service provider that fails to abide by the "Duty of
5 Candour" policy when a patient is harmed, shall be cautioned, given two weeks
6 to comply with the process and pay a fine of N200,000.00.

7 (6) Any health service provider that contravenes any regulation or
8 policy made pursuant to this bill shall be subject to a withdrawal or suspension
9 of its license, pay a fine of N500, 000. 00 and publication of such activity in the
10 national news and print media.

11 (7) Any person providing health services without adequate
12 qualification shall on conviction be liable to a fine of N1,000,000.00 or to a
13 term of imprisonment not exceeding 12 months or both.

14 (8) (a) Any person who obstructs an official of the Agency from entry
15 for inspection, shall on conviction be liable to a fine of N200,000.00 or to a
16 term of imprisonment not exceeding six months or both; and

17 (b) the health service provider shall be subjected to a six month
18 suspension and to such fines as to cover the cost of subsequent visits for
19 inspection.

20 (9) Any person who destroys or conceals evidence of harm inflicted
21 on a patient, or coerces another person to do so, shall on conviction be liable to
22 a fine of N2,000, 000.00 or to a term of imprisonment not exceeding two years
23 or both.

24 (10) The Agency may in addition to any penalty that may be
25 prescribed under this Act, direct any person who has contravened any of the
26 provisions of this Bill and any regulation made thereunder, to compensate any
27 person who may have suffered any direct loss or injury as a result of the
28 contravention.

29 (11) Notwithstanding the provisions of subsections (2), of this section
30 the complainant of a contravention may seek by action, consequential or

1 punitive damages or any other remedy that may be available under the law
2 after exploring the domestic remedies provided by the Agency.

3 (12) Penalties under this clause shall be imposed by the Agency
4 except for the penalties provided in sub clauses (7) (8) and (9) of this clause.

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

8 **23.** The President may give directives of a general nature or Directives by the
9 relating generally to matters of policy with regard to functions of the Agency President, etc.
10 and it shall be the duty of the Agency to comply with the directives.

11 **24.** The Director General may make regulations as may be Power of the
12 necessary or expedient for giving full effect to the provisions of this Bill and Director-General
13 for its administration thereof. to make Regulations

14 **25.**-(1) For the purposes of providing offices and premises Offices and
15 necessary for the performance of its functions under this Bill, the Agency Premises of the
16 may, subject to the Land Use Act- Agency

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

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

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

23 **26.**-(1) Subject to the provisions of this Bill, the provisions of the Limitation of
24 Public Officers Protection Act shall apply in relation to any suit against the suits against the
25 member or Officer or employee of the Agency. Agency

26 (2) Notwithstanding anything contained in any other law or
27 enactment, no suit shall lie against any member of the Board, the chairman
28 or any other officer or employee of the Agency for anything done in
29 pursuance or execution of this Bill or any other law or enactment, or any
30 alleged neglect or default in the execution of this Bill or such law or

	1	enactment, duty or authority, shall lie or be held against the Agency in any court
	2	unless-
	3	(a) it is commenced within three months after the act, neglect or
	4	default complained of; or
	5	(b) in the case of a continuation of damage or injury, within six
	6	months next after the leasing thereof.
Services of document	7	27. A notice, summons or other document required or authorized to
	8	be served upon the Agency under the provisions of this Bill or any other law or
	9	enactment may be served by delivering it to the Surgeon General.
Restriction of execution against property of the Agency	10	28. In any action or suit against the Agency, no execution or
	11	attachment of process shall be made against the Agency, unless not less than
	12	three months' notice of the intention to execute or attach has been given to the
	13	Agency.
Interpretation	14	29. In this Bill unless the context otherwise requires-
	15	"Agency" means the Patient Safety Agency of Nigeria;
	16	"Board" means the Governing Board of the Agency;
	17	"Clinical governance" means a systematic approach to maintaining and
	18	improving the quality of patient care within a health system, including
	19	education/training, clinical audits and clinical risk management;
	20	"Duty of candour" means a duty on health service providers to be open and
	21	honest with patients when something that goes wrong with their treatment or
	22	care causes, or has the potential to cause, harm or distress.
	23	The health service provider must-
	24	(i) tell the patient (or, where appropriate, the patient's advocate, career
	25	or family) when something has gone wrong;
	26	(ii) apologise to the patient (or, where appropriate, the patient's
	27	advocate, career or family);
	28	(iii) offer an appropriate remedy or support to put matters right (if
	29	possible), and
	30	(iv) explain fully to the patient (or, where appropriate, the patient's

1 advocate, carer or family) the short and long term effects of what has
2 happened.

3 "Health service providers" means clinics, hospitals, diagnostic and
4 treatment centres, laboratories, etc;

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

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

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

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

18 "Patient Safety" means the processes, structures and health governance
19 systems for preventing patient harm;

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

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

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

26 **30.** This Bill may be cited as the Patient Safety Agency of Nigeria Citation
27 Bill, 2018.

1 SCHEDULE

2 *Clause 2 (8)*

3 SUPPLEMENTARY PROVISIONS RELATING TO THE BOARD

4 *Proceedings of the Governing Board*

5 1.-(1) Subject to this Bill and section 24 of the Interpretation Act, the
6 Board may make standing orders regulating its proceedings or those of any of
7 its committees.

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

11 2.-(1) The Board shall meet not less than 4 times in each year and
12 subject thereto, the Board shall meet whenever it is summoned by the
13 Chairman, and if the Chairman is required to do so by notice given to him by
14 not less than half of the Board membership, he shall summon a meeting of the
15 Board to be held within 14 days from the date on which the notice is given.

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

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

24 *Committees*

25 3.-(1) The Board may constitute one or more Committees to carry out,
26 on behalf of the Board, such of its functions or the functions of the Commission
27 as the Board may determine.

28 (2) A committee constituted under this paragraph shall consist of such
29 number of persons (not necessarily members of the Board) as may be
30 determined by the Board; and a person other than a member of the Board shall

1 hold office on the committee in accordance with the terms of his
2 appointment.

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

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

8 *Miscellaneous*

9 4.-(1) The fixing of the seal of the Agency shall be authenticated by
10 the signature of the Chairman and any other person authorized generally or
11 specially to act for that purpose by the Board.

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

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

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

EXPLANATORY MEMORANDUM

This Bill seeks to establish the Patient Safety Agency of Nigeria to regulate patient safety through health service quality assurance: licensing, monitoring, investigations and auditing of health services provisions and providers.