THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

ARRANGEMENT OF CLAUSES

Clause

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

A Bill for

AN ACT of Parliament to give effect to Article 43(1)(a) of the Constitution; to provide for the responsibility of the national and county governments in the realisation of quality of healthcare for patients; to provide for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, registration, licensing and accreditation of health facilities; to set and provide for implementation of standards for quality of healthcare; and for connected purposes

ENACTED by the Parliament of Kenya as follows—

PART I—PRELIMINARY

Short title.

1. This Act may be cited as the Quality Healthcare and Patient Safety Act, 2025.

Interpretation.

2. In this Act, unless the context otherwise requires–

"accreditation for quality of healthcare" means a process of attestation that healthcare services, processes, systems, and persons conform to quality healthcare standards, requirements or criteria and attain the ratings prescribed in Regulations under this Act;

"adverse event" means an unintended harm caused by medical management rather than by a disease process;

"Authority" means Quality Healthcare and Patient Safety Authority established under section 27;

"Board" means the Board of Directors of the Authority appointed under section 28;

"Cabinet Secretary" means the Cabinet Secretary for the time being responsible for matters relating to quality of healthcare;

"Chief Executive Officer" means the Chief Executive Officer of the Authority appointed under section 37;

"clinical guidelines" means evidence-based protocols issued by the Cabinet Secretary for the delivery of healthcare services;

"Director General" means the Director-General for health appointed under section 16 of the Health Act; Cap. 241.

"emergency medical care" means the evaluation, treatment and care of an ill or injured person in a situation in which such evaluation, treatment and care is required and the continuation of treatment and care during the transportation of such a person to or between health facilities;

"healthcare professional" has the meaning assigned to it under the Health Act; Cap. 241.

"healthcare provider" has the meaning assigned to it under the Health Act; Cap. 241.

"healthcare services" has the meaning assigned to it under the Health Act; Cap. 241.

"health facility" has the meaning assigned to it under the Health Act; Cap. 241.

"medical aesthetic procedure" means any procedure or intervention, whether invasive or non-invasive, performed primarily for cosmetic or appearance-enhancing purposes, which involves the use of medical or quasi-medical techniques, substances, equipment or devices, and which may pose a risk to the health, safety, or well-being of a person;

"patient" means a person receiving or seeking a healthcare service from a health facility;

"patient-centred care" means holistic healthcare that respects and responds to each person's preferences, needs and values by fostering partnerships between healthcare providers and patients, for better satisfaction and health outcomes;

"quality of health care" means healthcare services that are safe, effective, timely, efficient, equitable and people-centered, provided to an individual, that improves health outcomes based on evidence-based standards; and

"Tribunal" means the Health Care Tribunal established under section 85.

Objects of the Act.

3. The objects of this Act are to—

(a) set standards for healthcare services and health facilities;

(b) improve the quality of healthcare services and health outcomes;

(c) guarantee patient rights and patient safety;

(d) ensure health facilities provide healthcare services in a manner that guarantees high-quality care, safety, effectiveness and efficiency; and

(e) establish mechanisms for the implementation and monitoring of standards of quality healthcare.

Guiding Principles.

4. The principles for implementation of this Act shall be —

(a) equitable, quality, cost effective and accessible healthcare to all persons;

(b) protection, promotion, improvement and maintenance of the health and well-being of every person;

(c) patient-centered care; and

(d) accountability.

Role of the Cabinet Secretary.

5. The Cabinet Secretary shall—

(a) develop and ensure implementation of policies, standards, guidelines and protocols that ensure the provision of quality healthcare services;

(b) ensure continuous improvement in the quality of healthcare services provided to individuals for, or in connection with the prevention, diagnosis or treatment of illness, or the protection or improvement of public health;

(c) ensure continuous improvement in the outcomes that are achieved from the provision of the healthcare services, including—

(i) the effectiveness of the healthcare services;

(ii) the safety of the healthcare services;

(iii) the quality of the experience undergone by patients; and

(iv) the healthcare provider's experience.

(d) reduce the inequalities in relation to the benefits that all persons may obtain from the healthcare services provided; and

(e) take such appropriate steps for the purpose of protecting the public from disease or other dangers to health including closing a health facility where the closure is required in public interest.

Role of counties.

6. A county government shall—

(a) implement the national government policies, guidelines, protocols and standards prescribed under this Act and other relevant laws;

(b) promote equitable access to quality healthcare services across all populations within the county;

(c) support continuous improvement in the safety, effectiveness and responsiveness of healthcare services;

(d) collaborate with the Authority to achieve the objects of this Act;

(e) monitor the quality of healthcare in all health facilities within its jurisdiction, including public, private and faith-based health facilities;

(f) maintain a county-level quality improvement program to address service gaps and monitor key performance indicators;

(g) establish digital reporting systems, integrated to the Comprehensive Integrated Health Information System established under the Digital Health Act, to track quality metrics and adverse events;

No. 15 of 2023.

(h) ensure health facilities and community health services within the county comply with the national standards on quality of healthcare prescribed under this Act and other relevant laws;

(i) collect and keep a record of quarterly indicators on quality including data on patient safety incidents, waiting times, clinical outcomes and patient satisfaction, through the Comprehensive Integrated Health Information System;

(j) conduct public awareness campaigns to educate communities on patient rights and quality of healthcare standards; and

(k) verify the licensure of healthcare providers employed in county health facilities from the relevant regulatory bodies.

PART II—PATIENT RIGHTS AND SAFETY

Realization of the rights and safety of the patient.

7. (1) The national government and county governments shall take measures to progressively achieve the full realization of the rights of the patients set out in this Act.

(2) The Cabinet Secretary shall ensure development, review and implementation of relevant policies, laws and programs to give effect to subsection (1).

(3) The Cabinet Secretary shall make Regulations to give effect to rights of the patients set out in this Part.

Right to safe and accessible health facilities.

8. (1) Every patient has the right to provision of healthcare services in a safe and accessible health facility.

(2) Every health facility shall—

(a) implement healthcare standards set out in this Act and other relevant laws;

(b) maintain high standards of cleanliness, ventilation and lighting, water and food safety, sanitation and waste management in accordance with the Public Health Act;

Cap. 242.

(c) provide reasonable modifications to enable accessibility by persons with special needs;

(d) respond to medical emergencies and make provision for access to emergency medical care through the national health emergency communication centre maintained by the Digital Health Agency;

(e) enforce policies to prevent violence, abuse or neglect of patients; and

(f) provide appropriate nutrition.

(3) The national and county governments shall develop and implement policies and laws to ensure the realization of this section.

Right to care by a qualified health professional.

9. (1) Every patient has the right to quality healthcare provided by a qualified and licensed healthcare professional.

(2) In pursuance of the right to healthcare by a qualified health professional under this section, every patient has the right to healthcare—

(a) from healthcare providers with qualifications verified and approved by the relevant regulatory bodies; and

(b) delivered with respect for human dignity and cultural diversity.

Right to information and decision-making.
Cap. 241.

10.(1) Notwithstanding section 8 of the Health Act, every patient has the right to clear, comprehensive, and accessible information about their care to enable them make informed decisions on their health.

(2) Without prejudice to the generality of subsection (1), every patient has the right to—

(a) be provided with comprehensive details on diagnosis, treatment options and health products and technologies prescribed;

(b) interpretation or alternative formats of information for accessibility; and

(c) disclosure of risks and benefits of healthcare procedures.

Right to be heard.

11. (1) Every patient has the right to report concerns regarding the safety and quality of healthcare arising out of the services offered by a health facility.

(2) Without prejudice to the generality of subsection (1), every patient is entitled to—

(a) raise concerns in an environment free from retaliation;

(b) receive written explanations and redress of their concerns; and

(c) have complaints involving serious harm investigated and addressed in accordance with this Act.

(3) A health facility shall provide a mechanism for patients to lodge a complaint.

(4) The Authority shall issue a standardized template of the internal dispute resolution mechanism for health facilities, updated every two years, to promote efficient redress of complaints.

Right to informed consent.
Cap. 241.

12. Without prejudice to section 9 of the Health Act, a patient has the right to be given full and accurate information on the patient's illness, diagnosis and proposed treatment options including alternative treatment and the costs involved in a language that the patient understands to enable the patient make an informed decision.

Right to safe and quality care.

13. (1) Every person has the right to access quality healthcare services that are —

(a) safe and dignified as provided in this Act;

(b) appropriate to their clinical needs; and

(c) compliant with the quality of healthcare standards prescribed under this Act.

(2) A person whose right under subsection (1) is violated may lodge a complaint with the Authority or seek redress in accordance with this Act.

Right to timely and effective care.

14. (1) Every patient has the right to timely and effective healthcare services.

(2) Without prejudice to the generality of subsection (1), a patient has the right to—

(a) prompt access to healthcare to prevent harm;

(b) coordinated continuum of care during out-of-hours and post-discharge periods;

(c) timely referrals, where appropriate.

Right to safe processes and practices.

15. (1) Every patient has the right to safe clinical processes that ensure safety and efficiency.

(2) Without prejudice to the generality of subsection (1), every patient is entitled to—

(a) accurate identification and documentation using standardized protocols;

(b) care adhering to approved clinical guidelines;

(c) safe administration of medication;

(d) safe surgical, medical and diagnostic procedures and infection prevention measures; and

(e) appropriate management of health conditions.

Right to safe and quality health products and technologies.

16. (1) Every patient has the right to safe and quality health products and technologies.

(2) Every healthcare provider shall—

(a) prescribe, administer and monitor the use of health products and technologies in accordance with relevant laws;

(b) prescribe health products and technologies approved by the relevant regulatory body;

(c) report adverse reactions to the relevant regulatory body in accordance with the Guidelines provided by the relevant regulatory body; and

(d) provide patient education and counseling on the safe use and potential risks of health products and technologies.

Right to dignity and equity.

17.(1) Every patient has the right to dignity and equitable care.

(2) For the purpose of subsection (1), a patient is entitled to—

(a) respectful, person-centered care, including quality palliative and end-of-life care;

(b) non-discriminatory treatment regardless of age, sex, disability, ethnicity, health status or socioeconomic status; and

(c) tailored services for vulnerable or marginalized groups, including women, youth, persons with disabilities and minority groups.

Patient rights charter.

18.(1) A health facility shall develop a patient rights charter.

(2) A health facility shall display the patient rights charter under subsection (1) in prominent and accessible locations.

(3) The Authority shall issue a standardized template of the charter, updated every two years, to promote awareness and quality of healthcare.

Patient safety and quality assurance measures.

19. (1) A health facility shall—

(a) implement measures to ensure patient safety and quality of healthcare in their health facility;

(b) provide healthcare services or perform a medical procedure for which the health facility or healthcare provider at the health facility is duly qualified and licensed under this Act or any other relevant laws; and

(c) adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as prescribed by the Cabinet Secretary on the recommendation of the Director-General.

(2) A person who fails to comply with the provisions of this section commits an offence and shall be liable, on conviction, to a fine not exceeding fifty million shillings or to imprisonment for a term not exceeding to ten years, or to both.

Duty to uphold quality of healthcare.

20. (1) Every health facility shall take all reasonable measures to deliver healthcare services that meet the quality of healthcare standards prescribed under this Act.

(2) The Authority shall enforce the quality of healthcare standards, prioritizing effectiveness, safety, and responsiveness to patient needs.

Evidence-based practice.

21. (1) Every health facility shall adhere to clinical guidelines based on scientific evidence including protocols.

(2) The Cabinet Secretary shall on the recommendation of the Director-General develop and publish clinical guidelines from time to time.

Safety and risk management.

22. (1) Every health facility shall—

(a) implement infection prevention surveillance and control measures as prescribed by the Cabinet Secretary;

(b) establish systems for the safe use, storage and administration of health products and technologies, integrated to the Comprehensive Integrated Health Information System established under the Digital Health Act;

No. 15 of 2023.

(c) report adverse medical or public health events to the Authority through the Comprehensive Integrated Health Information System established under the Digital Health Act; and

No. 15 of 2023.

(d) implement procedures for detecting, analyzing and reducing health risks and adverse events.

(2) Every health facility shall audit the safety of the health facility and submit an annual safety audit report to the Authority, setting out measures to improve the safety of the health facility.

(3) Every healthcare provider shall report to the health facility any act, omission or circumstance that may pose a risk to patient safety.

(4) The Authority shall issue a standardized template for the healthcare provider to report to the health facility any act, omission or circumstance that may pose a risk to patient safety, updated every two years.

(5) The template under subsection (4) shall make provision for anonymous reporting by a healthcare provider of any acts, omissions or circumstances that may pose a risk to patient safety.

Quality improvement.

23. (1) The Cabinet Secretary shall develop a quality improvement framework for health facilities, which shall—

(a) set benchmarks for patient satisfaction, clinical outcomes, and service efficiency;

(b) include specific targets for reducing disparities in access, treatment, and outcomes across geographic, socioeconomic and special needs demographics;

(c) reflect the levels of care and resource availability in the different categories of health facilities; and

(d) incorporate timelines for implementation and review.

(2) Every health facility shall develop and implement a quality improvement program that shall—

(a) monitor key performance indicators as prescribed in Regulations;

(b) analyze all data to address service gaps, prioritizing maternal healthcare, primary healthcare, mental healthcare and emergency medical care; and

(c) report progress to the Authority each year.

(3) Every health facility shall implement a structured quality assurance program including clinical audits, patient feedback mechanisms, peer reviews and outcome analysis.

(4) Compliance with quality improvement standards shall form the basis for health facility accreditation, performance assessment and access to the Social Health Insurance Fund established under the Social Health Insurance Act.

No. 16 of 2023.

(5) The Authority shall monitor the implementation of the quality improvement framework by health facilities.

Training and competency.

24. Every health facility and county government shall—

(a) verify the qualifications and licensure of healthcare providers before employment; and

(b) provide periodic training on patient safety, clinical guidelines and quality improvement.

Professional indemnity.

25. (1) Every health facility shall maintain a valid professional indemnity cover to protect the health facility against claims arising from acts or omissions committed in the course of providing healthcare services.

(2) Every health facility shall—

(a) verify and ensure that all its employees or contracted healthcare providers are covered under an appropriate professional indemnity cover; and

(b) insure the health facility against the professional liability of its staff.

Duty of the patient. Cap. 241.

26. Every patient shall have the duty provided under section 13 of the Health Act.

PART III—ADMINISTRATION OF QUALITY OF HEALTHCARE

Establishment of the Authority.

27. (1) There is established an Authority to be known as the Quality Health Care and Patient Safety Authority.

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

(a) suing and being sued;

(b) taking, purchasing or otherwise acquiring, holding, charging and disposing of movable and immovable property;

(c) borrowing money;

(d) entering into contracts; and

(e) doing or performing all other things or acts necessary for the proper performance of its functions under this Act, which may lawfully be done or performed by a body corporate.

Functions of the Authority.

28. The functions of the Authority shall be to—

(a) regulate and guide the development of health facilities' infrastructure;

(b) register, license and accredit health facilities;

(c) regulate the conduct of health facilities;

(d) inspect health facilities for compliance with quality of healthcare standards;

(e) undertake or cause to be undertaken, regular inspections, monitoring and evaluation of

health facilities to ensure compliance with the provisions of this Act;

(f) establish and implement a system of accreditation of health facilities for quality of healthcare;

(g) accredit health facilities for purposes of empanelment and contracting under section 33 and 34 of the Social Health Insurance Act;

(h) enforce compliance with quality of healthcare standards;

(i) promote public awareness on quality of healthcare including on patient rights;

(j) maintain a register of registered, licensed and accredited health facilities,

(k) build capacity on matters related to quality of healthcare;

(l) inspect and accredit health facilities for purposes of internship and training;

(m) provide policy advice and make recommendations to the Cabinet Secretary on matters related to quality of healthcare; and

(n) advise the Cabinet Secretary and county governments on the standards of quality of healthcare for health facilities;

(o) perform such other functions as may be prescribed by any other written law or as necessary for the promotion of the objects of this Act.

Powers of the Board.

29. (1) The Board shall have all the powers necessary for the proper performance of its functions under this Act and any other written law.

(2) The Board shall have the power to—

(a) enter, inspect and search any health facility at which any undertaking relating to healthcare is carried out or an offence is being committed or is suspected to have been committed;

Cap. 412C

(b) manage, control and administer the assets of the Authority in accordance with the Public Procurement and Asset Disposal Act;

(c) impose administrative fines for failure to comply with this Act;

(d) open such bank accounts for the funds of the Authority as may be necessary;

(e) determine the provisions to be made for capital and recurrent expenditure and for the reserves of the Authority;

(f) with the approval of the Cabinet Secretary for the time being responsible for matters relating to the National Treasury, invest any surplus funds of the Authority not immediately required for the purposes of this Act, as the Board may determine;

(g) receive gifts, grants, donations or endowments made to the Authority or any other monies in respect of the Authority and make legitimate disbursements therefrom in accordance with the provisions of this Act;

(h) levy or charge fees for the services rendered by the Authority as may be determined from time to time by the Board;

(i) enter into association, collaboration or partnerships with such other bodies or organizations, within or outside Kenya, as it may consider desirable or appropriate and in furtherance of the purposes for which the Authority is established; and

(j) undertake any activity necessary for the performance of any of its functions.

Board of Directors of the Authority.

30. (1) The management of the Authority shall vest in a Board of Directors consisting of—

(a) a chairperson appointed by the President;

(b) the Principal Secretary in the Ministry for the time being responsible for matters relating to

quality of healthcare standards or a representative designated in writing;

(c) the Principal Secretary for the National Treasury or a representative designated in writing;

(d) the Director-General;

(e) one person appointed by the Cabinet Secretary, not being a Governor, nominated by the Council of County Governors with knowledge in matters of health, quality management and quality improvement;

(f) two persons appointed by the Cabinet Secretary, not being public officers, nominated by—

(i) the consortium of healthcare providers; and

(ii) a patients' association in Kenya; and

(g) one person appointed by the Cabinet Secretary with expertise in quality healthcare for patients; and

(h) the Chief Executive Officer, who shall be an *ex officio* member of the Board.

(2) The appointment of the chairperson and members under subsection (1)(e), (f)and (g) shall be by notice in the *Gazette*.

Qualification for appointment as Chairperson or Member of the Board.

31.(1) A person shall qualify for appointment as the chairperson of the Board, where the person—

(a) is a citizen of Kenya;

(b) holds a Bachelor's degree in a healthcare related field from a university recognized in Kenya;

(c) has professional knowledge and experience of at least fifteen years in health governance, health administration, public policy or other health-related field;

(d) has served in a senior management level for a period of at least ten years;

(e) is in good standing with the relevant regulatory body; and

(f) meets the requirements of Chapter Six of the Constitution.

(2) A person shall qualify for appointment as a member of the Board under section 30(1)(e), (f)and (g) where the person—

(a) is a citizen of Kenya;

(b) holds at least a Bachelor's degree from a university recognized in Kenya;

(c) has professional knowledge and experience of at least ten years in matters of finance, social sciences, health administration and management or quality management and improvement; and

(d) meets the requirements of Chapter Six of the Constitution.

Term of office.

32. (1) The chairperson and the members appointed under section 30(1)(e), (f) and (g) shall hold office for a term of three years and shall be eligible for re-appointment for one further term of three years.

(2) The members appointed under section 30(1)(b), (c) and (d) shall hold office during their tenure of office unless removed from office by the appointing authority.

Vacation of office.

33. A person shall cease to be a chairperson or member of the Board, where that person —

(a) is unable to perform the functions of the office by reason of prolonged physical or mental illness;

(b) is otherwise unable or unfit to discharge his or her duties;

(c) is adjudged bankrupt;

(d) is convicted of an offence and sentenced to imprisonment for a term exceeding six months, without the option of a fine;

(e) is absent from three consecutive meetings of the Board without lawful cause;

(f) resigns by notice in writing to the appointing authority;

(g) dies; or

(h) is removed from office in accordance with the provisions of the Constitution or any other written law.

Committees of the Board.

34. (1) The Board may establish committees for the effective performance of its functions under this Act.

(2) The Board may co-opt into the membership of a committee any person whose knowledge and expertise may be necessary for the effective performance of the functions of the Authority in accordance with the Government directives.

(3) A person co-opted into a committee under subsection (2), may attend the meetings of the committee and participate in its deliberations, but shall not vote at such meetings.

Conduct of business and affairs of the Board.

35. (1) The Board shall conduct its business and affairs in accordance with the provisions of the First Schedule.

(2) The Board may regulate its own procedure.

Delegation by the Board.

36. The Board may, by resolution either generally or in any particular case, delegate to any committee of the Board or to any member in writing and by name the exercise of any of the powers or the performance of any of the functions or duties of the Board under this Act.

The Chief Executive Officer of the Authority.

37. (1) The Board shall, through an open, transparent and competitive recruitment process, appoint a qualified person to be the Chief Executive Officer of the Authority.

(2) A person shall qualify for appointment as the Chief Executive Officer of the Authority, where the person—

(a) is a citizen of Kenya;

(b) holds a bachelor's degree in a healthcare related field from a university recognized in Kenya;

(c) is a registered member of a health professional body;

(d) has had at least ten years professional experience in matters of healthcare management and administration, quality management and improvement or other management related field;

(e) has served in a management level for a period of at least five years; and

(f) meets the requirements of Chapter Six of the Constitution.

(3) The Chief Executive Officer shall serve on such terms and conditions as the Board may determine.

(4) The Chief Executive Officer shall hold office for a period of three years and shall be eligible for re-appointment for one further term of three years.

(5) The Chief Executive Officer shall, in the performance of the functions and duties of the office, be responsible to the Board.

(6) The Chief Executive Officer shall—

(a) be the Registrar of the Authority, and shall perform such duties as are prescribed by this Act in connection with the registers maintained under this Act;

(b) be the accounting officer of the Authority;

(c) be responsible for—

(i) implementing the decisions of the Board;

(ii) the day-to-day administration and management of the affairs of the Authority; and

(iii) the coordination and supervision of the staff of the Authority; and

(d) perform any other duties as may be assigned by the Board and any other written law.

Removal from office of the Chief Executive Officer.

38. (1) The Chief Executive Officer may be removed from office by the Board in accordance with the terms and condition of service, for—

(a) inability to perform the functions of the office arising out of physical or mental infirmity;

(b) gross misconduct or misbehaviour;

(c) incompetence or neglect of duty;

(d) conviction for an offence relating to the functions of the Authority with a sentence to imprisonment for a term exceeding six months, without the option of a fine;

(e) being adjudged bankrupt;

(f) being declared as being of unsound mind;

(g) violation of the Constitution or any other written law; or

(h) breaching any other grounds specified in the terms and conditions of service of the Chief Executive Officer.

(2) Where the question of the removal of the Chief Executive Officer under subsection (1) arises, the Board shall act in accordance with the principles of fair administrative action prescribed under Article 47 of the Constitution and the Fair Administrative Action Act.

Cap. 7L.

Corporation Secretary.

39. (1) The Board shall, through an open, transparent and competitive recruitment process, appoint a qualified person to be the Corporation Secretary of the Authority on such terms as the Board may, upon the advice of the Salaries and Remuneration Commission, determine.

(2) A person shall qualify for appointment as the Corporation Secretary if that person—

(a) holds a bachelor's Degree in law from a university recognized in Kenya;

(b) is an Advocate of the High Court of Kenya;

(c) is a Certified Public Secretary;

(d) is a member in good standing of the Institute of Certified Public Secretaries of Kenya;

(e) has at least five years' experience in governance matters; and

(f) meets the requirements of Chapter Six of the Constitution.

(3) The Corporation Secretary shall be the Secretary to the Board.

Staff of the Authority.

40. The Board shall, through a competitive and transparent process, employ such officers, agents and other staff as may be necessary for the proper discharge of its functions under this Act, upon such terms and conditions of service as the Board may determine upon the advice of the Salaries and Remuneration Commission.

Remuneration.

41. The chairperson, members of the Board and staff of the Authority shall be paid such remuneration, fees, allowances and such other reimbursements as may be approved by the Cabinet Secretary upon the advice of the Salaries and Remuneration Commission.

Protection from personal liability.

42. (1) No matter or thing done by a member of the Board or an officer, employee or agent of the Authority shall, where the matter or thing was done in good faith in the execution of the functions or powers of the Authority, render the member, officer, employee or agent personally liable for any action, claim or demand whatsoever.

(2) Despite subsection (1), nothing in this section shall exempt a member of the Board, officer, employee or agent of the Authority from individual responsibility for unlawful or criminal act committed by the member of the Board, officer, employee or agent of the Authority.

Common seal.

43. (1) There shall be a common seal of the Authority which shall be kept in the custody of the Corporation Secretary and shall not be used except on the direction of the Board.

(2) The affixing of the common seal of the Authority shall be authenticated by the signatures of the Chairperson and the Chief Executive Officer and any document required by law to be made under seal and all decisions of the Board may be authenticated by the signatures of the Chairperson and the Chief Executive Officer.

(3) The Board shall, in the absence of either the Chairperson or the Chief Executive Officer, in any particular matter, nominate one member to authenticate the seal of the Authority on behalf of either the Chairperson or the Chief Executive Officer.

(4) The common seal of the Authority when affixed to a document and duly authenticated, shall be judicially and officially noticed, and unless the contrary is proved, any necessary order by the Authority under this section shall be presumed to have been duly given.

PART IV—REGISTRATION, LICENSING AND ACCREDITATION OF HEALTH FACILITIES

Approval of a health facility.

44. (1) A person who intends to operate a health facility shall obtain an approval from the Authority.

(2) An approval under this section shall be required for the construction, operation and decommissioning of a health facility.

(3) The approval requirements prescribed under subsection (2) shall make a distinction between—

(a) ambulances;

(b) medical camps; and

(c) any other health facility as may be prescribed by the Cabinet Secretary.

(4) An application for an approval under this section shall be in such form and manner as may be prescribed in Regulations.

(5) The Cabinet Secretary shall develop standards for the construction, operation and decommissioning of a health facility.

Registration of a health facility.

45. (1) A person who intends to operate a health facility shall, after acquiring approval under section 44

apply for registration of the health facility with the Authority.

(2) The registration of a health facility under subsection (1) shall be in the prescribed manner.

Application for registration.

46. (1) An application for registration shall contain—

(a) the approval issued under section 44;

(b) a description of a health facility specific information or activity including—

(i) the type of healthcare services that are to be offered at the health facility;
(ii) the number, qualifications and competence of the healthcare providers at the health facility;
(iii) layout designs and specifications of available infrastructure and equipment; and
(iv) a statement of financial ability and fees to be charged by the health facility;

(c) evidence that the health facility is to be operated or managed by a healthcare professional registered by a relevant regulatory body;

(d) contact details of the owner, operator or a person having administrative responsibilities at the health facility; and

(e) any other details as may be prescribed by the Authority.

(2) The Authority shall, before issuing a certificate of registration under this Act , undertake an inspection of the health facility.

Certificate of registration.

47. (1) Where the applicant satisfies the Authority that the health facility meets the requirements for registration, the Authority shall issue the health facility with a certificate of registration in the prescribed manner.

(2) The Authority shall issue a health facility registered under this Act a certificate of registration upon the payment of the prescribed fee.

(3) Where an applicant does not comply with provisions of this Act, the Authority may refuse to grant a certificate of registration to the applicant.

(4) Where the Authority refuses to grant a certificate of registration, the Authority shall inform the applicant, in writing, of the refusal and the reasons for the refusal within fourteen days from the date of the decision.

Suspension of the certificate of registration.

48. (1) The Authority may suspend a certificate of registration where—

(a) any information given by the applicant is found to be false or misleading;

(b) the holder of the certificate fails to comply with any of the requirements of this Act; or

(c) any term or condition thereof has not been complied with within the prescribed period.

(2) Where the Authority intends to suspend a certificate of registration under this section, it may, at least twenty-one days before the date of the intended suspension, notify the health facility of such intention, specifying the reasons thereof, and shall take every precaution to ensure fair administrative action in the exercise of this power.

(3) The Authority may in writing, reinstate a certificate of registration suspended under subsection (1) if satisfied that the reasons for the suspension no longer exist.

Revocation.

49. (1) A certificate of registration of a health facility may be revoked, where—

(a) the health facility fails to comply with any of the provisions of this Act and any other relevant laws; and

(b) the name of the health facility was fraudulently entered in the register.

(2) The Authority shall *Gazette* the details of a health facility whose certificate of registration has been revoked.

Licence.

50. (1) A person who wishes to operate a health facility shall after being registered under section 47 apply for an annual licence from the Authority.

(2) The Authority may, before issuing a licence under this section, undertake an inspection of the health facility.

(3) A person who operates, maintains or represents itself as a health facility without obtaining a licence from the Authority under this Act, commits an offence and shall be liable, on conviction, to a fine not exceeding ten million shillings or to imprisonment for a term not exceeding five years, or to both.

Application for a licence.

51. An application for a licence shall be accompanied by—

(a) a copy of the approval issued under section 44;

(b) a copy of a certificate of registration issued under section 47;

(c) the prescribed fees;

(d) particulars of the healthcare professionals employed in the health facility and proof of their licensure by the respective regulatory body;

(e) particulars of non-healthcare professional employees in the health facility;

(f) particulars of a digital health solution that has been certified by the Digital Health Agency to be used by the health facility; and

(g) any other requirement as may be determined by the Authority.

Conditions for grant of licence.

52. A health facility shall be licensed where—

(a) the premises of the health facility conform to the description, infrastructure and personnel criteria for the respective category of the

Cap. 241.

health facility as set out in the First Schedule to the Health Act and the Regulations prescribed by the Cabinet Secretary;

(b) the healthcare providers providing healthcare services at the health facility are holders of valid practice licences issued by the relevant regulatory body to render healthcare services at the health facility;

(c) all professional staff working in the health facility are qualified and are registered by the relevant regulatory body as required in the relevant law; and

(d) the quality of healthcare to be provided at the health facility complies with the quality of healthcare standards prescribed under this Act.

Validity of the licence.

53. A licence issued under this Act shall be valid up to the 31st December of each year of issue and may, upon expiry, be renewed on the making an application for renewal.

Categorization of health facilities.

54. For purposes of licensing under this Act, the Authority shall—

Cap. 241.

(a) categorize registered health facilities in accordance with the First Schedule to the Health Act; and

(b) determine the annual fees payable in respect of each category of a health facility.

Services offered by health facilities.

55. (1) A licence issued to a health facility shall specify the nature of the healthcare services that may be provided by the health facility based on the category of the health facility.

(2) Despite subsection (1), a health facility shall not be prohibited from offering emergency medical care in accordance with the Regulations prescribed by the Cabinet Secretary.

(3) The Authority shall publish in the *Gazette* a list of licensed health facilities and the type and nature of the

healthcare services to be provided by the licensed health facilities.

Suspension of a licence.

56. (1) The Authority may suspend a licence issued under this Act where the health facility—

(a) willfully neglects or refuses to comply with any of the provisions of this Act; or

(b) obstructs, impedes, or hinders any person carrying out any duties or responsibilities under this Act.

(2) Where the Authority suspends a licence, the Authority shall inform the health facility of its decision and the reasons for the decision in writing as prescribed in Regulations.

Revocation of a licence.

57. (1) The Authority may revoke a licence issued under this Act where—

(a) the health facility fails to address the grounds of suspension of the licence;

(b) the health facility obtained the licence in a fraudulent manner; or

(c) the health facility concealed material information from the Authority.

(2) Where the Authority revokes a licence, the Authority shall inform the health facility of its decision and the reasons for the decision in writing as prescribed in Regulations.

(3) A person who continues to operate a health facility under a revoked licence commits an offence and shall be liable, on conviction, to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years, or to both.

Accreditation for quality of healthcare.

58. The Authority shall, for purposes of ensuring quality of healthcare, accredit health facilities.

Role of the Authority in accreditation for quality of healthcare.

59. (1) The Authority shall accredit a health facility for quality of healthcare in accordance with the quality of healthcare standards prescribed by the Cabinet Secretary.

(2) The Authority shall, in relation to accreditation for quality of healthcare—

(a) ensure that the accredited health facilities, comply with the quality of healthcare standards;

(b) ensure that the quality of healthcare standards conform to the latest standards prescribed by the Cabinet Secretary; and

(c) publicize and disseminate the quality of healthcare standards.

(3) The Authority may, in collaboration with the relevant government agencies, develop frameworks for the purposes of assessing the conformity with the applicable quality of healthcare standards.

Application for accreditation.

60. (1) A person shall apply to the Authority for accreditation of a health facilityunder this Act.

(2) A person shall, prior to applying for accreditation under subsection (1), undertake self-assessment on the health facility, to be assessed by the Authority for accreditation under this Act.

(3) The Authority shall develop a self-assessment template, updated every two years, for purposes of self-assessment under subsection (2).

(4) The application under subsection (1) shall be accompanied by documents including—

(a) a description of the type and level of health facility;

(b) a description of the category or class of the health facility;

(c) a description of the healthcare services to be provided;

(d) contact details of the person making the application;

(e) a self-assessment report;

(f) proof of licensure by the Authority;

(g) proof of registration by the Authority;

(h) proof of listing of the health facility in the facility registry in the Comprehensive Integrated Health Information System established under the Digital Health Act;

No. 15 of 2023.

(i) the prescribed fee for accreditation; and

(j) any other details as may be prescribed by the Authority.

(5) The Authority shall, on receipt of the application under subsection (1), conduct a quality assessment of the health facility, and communicate its decision on the accreditation within ninety days from the date of receipt of the application.

(6) A person who knowingly supplies false or misleading information under this section commits an offence and shall be liable, on conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding one year, or to both.

Requirements for accreditation.

61. The Authority shall accredit a health facility, based on compliance with the applicable quality of healthcare standards including—

(a) conformity to infrastructure standards;

(b) conformity to human resource standards;

(c) conformity with disease-specific clinical guidelines;

(d) conformity to health products and technology standards;

(e) conformity to medical laboratory standards;

(f) the monitoring of patient outcomes; and

(g) the monitoring of the satisfaction of patients and healthcare providers.

Certificate of accreditation.

62. The Authority shall, where the health facility, complies with the requirements under this Act, issue a certificate of accreditation to the health facility.

Validity of the certificate of accreditation.

63. The certificate of accreditation issued under this Act shall be valid for a period of two years from the date of issue.

Renewal of accreditation.

64. A health facility shall, ninety days prior to the expiry of the accreditation make an application for renewal of the accreditation of the health facility.

Suspension of accreditation.

65. (1) The Authority shall suspend the accreditation of a health facility where the —

(a) health facility fails to meet the quality of healthcare standards;

(b) health facility fails to correct identified non-conformities within the stipulated timelines;

(c) health facility fails to comply with the provisions of this Act and any other written law; and

(d) licence of the health facility is revoked or expired without being renewed.

(2) Where the accreditation of a health facility is suspended under subsection (1), the Authority shall notify the relevant stakeholders of the suspension.

Revocation of accreditation.

66. (1) The Authority may revoke the accreditation of a health facility, where the —

(a) health facility fails to address the grounds of suspension of the accreditation;

(b) accreditation was obtained in a fraudulent manner; or

(c) health facility concealed material information from the Authority.

(2) Where the accreditation of a health facility is revoked under subsection (1), the Authority shall notify the relevant stakeholders of the revocation.

Quality improvement in a health facility.

67. A health facility shall for purposes of quality improvement—

(a) keep records of its quality improvement activities;

(b) develop a quality improvement program and budget in line with the identified quality improvement priorities;

(c) evaluate and oversee the implementation of quality improvement programs or activities; and

(d) conduct self-assessments on the quality of healthcare at the health facility.

Quality scoring and rating.

68. (1) The Authority shall establish a quality scoring and rating framework for health facilities.

(2) The framework under subsection (1) shall provide for the—

(a) quality assessment of health facilities;

(b) performance rating based on the results of the quality assessment; and

(c) scoring based on the quality assessment of the health facility.

(3) The Authority shall, based on the result of the scoring and performance rating—

(a) note and commend a health facility on the areas that are working effectively;

(b) identify areas that require improvement and develop, in consultation with the health facility a quality improvement program with a defined period on the areas for improvement; and

(c) in the case of a non-conformity with the quality of healthcare standards under this Act, allow the health facility to demonstrate compliance within thirty days of the notification of non-conformity by the Authority.

Award of a performance rating.

69. (1) The Authority shall award a performance rating and a recognition certificate to a health facility in accordance with the level of the health facility.

(2) The performance rating under subsection (1) shall be—

(a) assigned based on the results of the assessment for quality of healthcare; and

(b) used to determine the incentives to a health facility.

(3) The performance rating under subsection (1) may be revised by the Authority from time to time upon the conduct of a further quality assessment of the health facility.

Non-compliance with quality standards.

70. Where a health facility is found to be non-compliant with the quality of healthcare standards, the Authority shall take the necessary actions including—

(a) issuing warnings for minor non-compliances, with a clear timeline for rectification;

(b) requiring quality improvement programs;

(c) imposing fines or penalties for significant violations of quality of healthcare standards or failure to submit required reports;

(d) suspending or revoking accreditation where the health facility fails to comply with quality of healthcare standards or the corrective actions after several inspections; and

(e) closing the health facility in cases where non-compliance poses an immediate risk to patient safety or health outcomes.

Monitoring of compliance by the Authority.

71. The Authority shall monitor compliance with the requirements of accreditation for quality of healthcare by health facilities.

Register of health facilities.

72. (1) The Chief Executive Officer shall keep and maintain a register of health facilities.

(2) The register under subsection (1) shall contain—

(a) registered health facilities;

(b) licensed health facilities; and

(c) accredited health facilities.

(3) The register in subsection (1) shall contain information on the health facility including their—

(a) name;

(b) contact information;

(c) type and nature of healthcare services provided;

(d) date of registration;

(e) license number;

(f) accreditation number;

(g) listing number in the facility registry in the Comprehensive Integrated Health Information System established under the Digital Health Act;

No. 15 of 2023.

(h) quality rating and scores; and

(i) compliance level based on the quality assessment score.

(4) The Chief Executive Officer may, at the request of the holder of the certificate of registration, licence or accreditation certificate issued under this Act, remove any entry in the register which has ceased to be applicable.

(5) A person may, during normal office hours and on payment of the prescribed fee, inspect the register and any document relating to an entry and may obtain from the Chief Executive Officer a copy or extract from the register of any such document.

(6) The Chief Executive Officer shall annually cause to be published in electronic or print media and in the official communication channel of the Authority, particulars of health facilities duly registered under this Act.

Removal from the register.

73. (1) The Chief Executive Officer may for a specified duration and on the recommendations of the Authority, remove from the register, a health facility—

(a) whose name has been fraudulently entered in the register;

(b) whose name the Board has directed that it should be removed from the register for breach of the provisions of this Act; or

(c) who has failed to satisfy the requirements for accreditation for quality of healthcare for the time being in force.

(2) Where the Chief Executive Officer establishes that an entry has been erroneously or incorrectly entered in the register, the Chief Executive Officer may correct the error and notify the affected person of such corrections.

PART V—INSPECTIONS, INVESTIGATIONS AND ENFORCEMENT

Appointment of health facility inspectors.

74. (1) The Authority shall, by notice in the *Gazette* appoint health facility inspectors of such qualifications as may be prescribed by the Authority.

(2) An inspector appointed under subsection (1) shall—

(a) carry out inspections of health facilities and healthcare services so as to—

(i) monitor compliance with the provisions of this Act and all applicable Regulations; and

(ii) compile and submit reports of inspection to the Authority; and

(b) perform such other functions as the Authority may deem necessary.

Inspection objectives and programmes.

75. (1) The Authority shall establish a planned and systematic inspection programme consisting of routine and reactive inspections that are announced and unannounced to monitor compliance with —

(a) this Act and all applicable Regulations; and
(b) the terms and conditions of registration, licensing and accreditation issued by the Authority.

(2) The inspection programme under subsection (1) shall ensure that —

(a) health facilities meet the necessary regulatory requirements;

(b) healthcare providers possess the competency necessary to carry out their functions; and

(c) deficiencies and deviations from standards are remedied without undue delay.

Powers of inspectors.

76. An inspector appointed under this Act may—

(a) inspect a health facility for purposes of registration, licensing or accreditation;

(b) enter any health facility which the inspector has reason to believe is necessary in order to ascertain whether the provisions of this Act are being complied with;

(c) take any equipment or material required for any purpose for which the power of entry is being exercised;

(d) carry out such inspections and make such recording as may be necessary;

(e) interview the owner or operator of a health facility or any of the employees of the health facility;

(f) direct that any part of the facility which the inspector has power to enter, or anything in such a health facility, be left undisturbed for as long as is reasonably necessary for the purpose of any inspection;

(g) take appropriate samples, articles or substances found in any health facility which the inspector has power to enter; and

(h) request the production of any records which may be required to be kept under this Act.

Qualification of inspectors.

77. (1) A person is qualified for appointment as an inspector, if the person—

Cap. 241.

(a) is a registered healthcare professional in accordance with the Health Act and any other relevant laws; or

(b) holds such other qualification as the Authority may prescribe.

Conduct of inspections.

78. An inspector may for the purpose of ensuring compliance with the provisions of this Act, conduct an inspection in a health facility and shall in particular—

(a) inspect the conditions and services provided by the health facility; and

(b) prepare and submit a report outlining the findings for purposes of—

(i) approving a health facility on the basis of the criteria prescribed by the Authority from time to time;

(ii) suspending or withdrawing registration, licensing or accreditation due to non-compliance with the quality of healthcare standards set by the Authority; or

(iii) making recommendations on the issuance of a notice of closure of the health facility by the Authority.

Code of conduct for inspectors.

79. (1) The Authority shall prescribe a code of conduct for inspectors.

(2) For purposes of subsection (1), the code of conduct shall contain rules relating to compliance by inspectors with a set minimum standard of conduct which is necessary to realise the objects of the Authority.

Obstruction of inspectors.

80. (1) A person who—

(a) hinders or obstructs the Authority or an inspector in the exercise of their duties under this Act or Regulations made thereunder;

(b) fails to comply with a lawful order or requirement made by the Authority or an inspector in accordance with this Act or Regulations made thereunder;

(c) denies the Authority or an inspector entry upon any land, premises, vehicle or aircraft or other means of conveyance that the Authority or the inspector is empowered to enter under this Act or Regulations made thereunder;

(d) impersonates the Authority or an inspector; or

(e) denies the Authority or an inspector access to records or documents kept pursuant to this Act or Regulations made thereunder, commits an offence.

(2) A person who commits an offence under this section shall be liable, on conviction, to a fine not exceeding two million shillings or to imprisonment for a term not exceeding two years, or to both.

Enforcement.

81.(1) Where an inspector determines that the conduct of a health facility is, or a healthcare service is being provided in violation of the provisions of this Act or that the conduct or healthcare service poses an immediate risk of injury or damage to patients, property or the environment, the inspector may—

(a) immediately order the temporary suspension of the healthcare service or the health facility, where appropriate; or

(b) take any other action as may be prescribed under the provisions of this Act.

(2) An order issued by an inspector under subsection (1) shall continue to be in force unless—

(a) reversed or modified by the Authority; or

(b) modified or altered through an administrative or judicial review.

(3) An inspector who undertakes any enforcement action specified in subsection (1) shall prepare a report indicating the reasons for the action and identifying the evidentiary basis for the findings including measurements, test samples, explanations and any other relevant information.

(4) The report prepared under subsection (3) shall be made available to the health facility who shall have the

right to submit explanations or objections within the time specified by the Authority.

(5) The Authority may prescribe the circumstances under which the prior approval of the Authority shall be obtained by an inspector prior to taking any of the actions specified in subsection (1).

Oversight role by the Authority.

82. (1) Upon receipt of an inspection report under section 81 (3), the Authority shall—

(a) where the report is accompanied by objections, review the objections issue such orders as may be necessary;

(b) ensure that relevant measures have been taken against the persons contravening the provisions of the Act.

(c) adopt the immediate remedial measures as recommended by the inspector;

(d) enforce the temporary closure of the health facility; or

(e) impose a penalty as the Board may prescribe.

(2) The person subject to enforcement action shall take the necessary measures to—

(a) remedy compliance as directed by the Authority or as soon as practically possible; and

(b) prevent recurrence.

(3) The Authority may, where the case presents an immediate safety or security hazard to people, property or the environment, require the person to suspend its activities or services until the situation has been remedied.

Record keeping.

83. A health facility shall keep records of healthcare services offered, recommendations from inspections and mitigation measures, if any.

Inspection of records.

84. (1) The Authority may—

(a) by notice in writing to a health facility specify the records to be kept by the health facility under this Act; and

(b) request the health facility to make available to the Authority for its inspection such records as may be specified in the notice.

(2) Any person who refuses to comply with a request made under subsection (1) commits an offence and shall be liable, on conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding one year, or to both.

PART VI—THE HEALTHCARE TRIBUNAL

Establishment of the Health Care Tribunal.

85. (1) There is established a Tribunal to be known as the Health Care Tribunal for the purpose of hearing and determining complaints and disputes in accordance with this Act or any other written law.

Cap. 246A.

No. 16 of 2023.

(2) The Tribunal shall be a successor of the HlV and AIDS Tribunal established under section 25 of the HIV and AIDS Prevention and Control Act and the Dispute Resolution Tribunal established under section 44 of the Social Health Insurance Act.

(3) Any proceedings before the Tribunals under subsection (2) that have not been concluded at the commencement of this Act shall be determined by the Health Care Tribunal.

(4) The Tribunal shall consist of members appointed by the Judicial Service Commission as follows—

(a) a Chairperson who shall be a person who is qualified to be a judge of the High Court;

(b) one advocate of the High Court of not less than five years' standing;

(c) three other persons who shall possess knowledge and experience in matters of health, insurance, policy and quality improvement and who are not in the employment of the Government or the Board and are not health service providers.

(5) The members of the Tribunal shall hold office for a period of three years and shall be eligible for re appointment for one further term of three years.

(6) The quorum for a meeting of the Tribunal shall be three members.

(7) The members of the Tribunal shall be entitled to receive such allowances as the Cabinet Secretary, upon the advice of the Salaries and Remuneration Commission, may determine.

(8) The Cabinet Secretary shall make rules for the operationalization of the Tribunal.

Dispute resolution.

86. (1) A person aggrieved by a decision or action made under this Act may, within thirty days from the date of the decision or action appeal to the Tribunal for a review of such decision or action.

(2) The Tribunal may uphold, reverse, revoke or vary the decision or action of the Board.

(3) A person dissatisfied with an order made by the Tribunal under subsection (2) may appeal to the High Court within twenty-one days from the date the order is made.

Vacancy in the Dispute Resolution Tribunal.

87. The office of a member of the Tribunal shall become vacant if the member—

(a) dies;

(b) resigns;

(c) is unfit by reason of mental or physical infirmity to perform the duties of the office;

(d) is convicted of an offence and sentenced to imprisonment for a term exceeding six months, without the option of a fine;

(e) has failed to attend at least three consecutive meetings of the Tribunal, without lawful cause; or

(f) is removed from office on any of the following grounds—

(i) gross violation of the Constitution or any other written law; or

(ii) gross misconduct or misbehaviour.

PART VII—FINANCIAL PROVISIONS

Funds of the Authority.

88. (1) The funds of the Authority shall comprise of —

(a) monies appropriated by the National Assembly;

(b) monies as may accrue to or vest in the Authority in the course of the exercise of its powers or the performance of its functions under this Act;

(c) monies from fees paid to the Authority in respect of the services offered by it;

(d) monies as may be payable to the Authority pursuant to this Act or any other written law;

(e) gifts, grants, donations or endowments as may be given to the Authority; and

(f) monies from any other lawful source provided for the Authority.

(2) All the funds donated, lent or issued to the Authority under this Act shall be accounted for and appropriated in accordance with the Public Finance Management Act.

Cap. 412A.

Investment of funds.

89. (1) All monies in the Authority which are not immediately required to be applied for the purposes of this Act shall be invested—

(a) in such investment in a reputable bank on the advice of the Central Bank of Kenya, being an investment in which trust funds, or part thereof, are authorized by law to be invested; and

(b) in government securities as may be approved by the Cabinet Secretary for the National Treasury.

(2) All investments made under this section shall be held in the name of the Authority.

Financial year.

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

Annual estimates.

91. (1) The Authority shall, within three months after the end of the financial year, cause to be prepared estimates of its revenue and expenditure for that financial year.

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

(a) payment of salaries, allowances and other charges in respect of the staff of the Authority;

(b) payment of allowances and any other emoluments to the members of the Board;

(c) payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Authority;

(d) proper maintenance of buildings and grounds of the Authority;

(e) acquisition, maintenance, repair and replacement of the equipment and other movable property of Authority; or

(f) creation of such reserve funds to meet future or contingent liabilities in respect of retirement benefits, insurance or replacement of buildings or equipment, or in respect of such other matters as the Authority may consider appropriate.

(3) The annual estimates shall be approved by the Board before the commencement of the financial year to which they relate and after the approval, the annual estimates shall not be increased without prior consent of the Board.

(4) No expenditure shall be incurred for the purposes of the Authority except in accordance with the annual estimates approved under subsection (3).

Accounts and audit.

92. (1) The Board shall cause to be kept all proper books and records of accounts of the income, expenditure, assets and liabilities of the Authority.

(2) Within three months at the end of each financial year, the Board shall submit to the Auditor-General, the accounts of the Authority together with—

(a) a statement of income and expenditure of the Authority during the year; and

(b) a statement of the assets and liabilities of the Authority on the last day of that year.

(3) The accounts of the Authority shall be audited and reported upon in accordance with the provisions of the Public Finance Management Act and the Public Audit Act.

Cap. 412A.

Cap. 412B.

Annual report.

93. (1) The Board shall, within three months after the end of each financial year, prepare and submit to the Cabinet Secretary a report on the operations of the Authority for the immediately preceding year.

(2) The Cabinet Secretary shall, within three months of submission of the report under subsection (1), transmit the report to Parliament.

(3) The report in this section shall contain—

(a) data on quality improvement, patient outcomes, patient satisfaction and health system performance;

(b) recommendations on specific actions including legal and administrative measures to be taken to address specific concerns identified by the Board; and

(c) any other information relating to the performance of functions under this Act that the Board considers relevant.

PART VII— GENERAL PROVISIONS

Regulations.

94. (1) The Cabinet Secretary may, in consultation with the Board, make Regulations for the better carrying into effect of the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), the Cabinet Secretary shall make Regulations for—

(a) the fees to be charged under this Act;

(b) the forms to be used in connection with this Act;

(c) registration and licensing of health facilities;

(d) approval, review and assessment of a health facility;

(e) standards of medical laboratories;

(f) standards of pharmacies;

(g) standards of ambulance services;

(h) standards of emergency medical care;

(i) standards of telemedicine services;

(j) standards of alternative medicine and traditional medicine;

(k) standards of medical aesthetic procedures;

(l) standards of community health services;

(m) accreditation for quality of healthcare processes;

(n) conduct of inspections;

(o) investigation procedures;

(p) quality of healthcare standards;

(q) categories of health facilities;

(r) quality rating; and

(s) any other matter that may be related to the quality of healthcare.

Categorization of ambulances.

95. (1) Ambulances shall be classified into the following categories—

(a) advanced life support ambulances, that are designed and equipped to provide advanced treatment and monitoring of patients;

(b) intermediate life support ambulances, that provide limited invasive treatment and monitoring of patients; and

(c) basic life support ambulances, that provide basic treatment and monitoring of patients.

(2) A licence issued under this Act shall set out the category of the ambulance.

Review.

96. (1) A person aggrieved by a decision of the Authority under this Act may apply to the Authority for a review of the decision.

(2) An application for review under subsection (1) shall be filed within thirty days from the date of the decision.

(3) The Authority shall within sixty days of receipt of an application for review, make a determination and communicate its decision to the applicant.

(4) An application for review under this section shall not have the effect of suspending the decision of the Authority.

Appeal.

97. A person aggrieved by a decision of the Authority under this Act may, within thirty days from the date of the decision, appeal to the Tribunal.

Confidentiality.

98. The Authority shall keep information acquired for purposes of the performance of its functions confidential and shall disclose such information only to the extent that it considers necessary for the proper performance of the functions of the Authority.

Offences.

99. (1) A person who—

(a) obstructs or hinders the Authority in the exercise of its powers under this Act;

(b) without lawful justification fails or refuses to comply with the directions of the Board;

(c) refuses or fails, without reasonable cause to comply with a request to furnish the Authority with any information or to produce any documents or records; or

(d) when appearing before the Board or any of its committees, for examination, makes a statement which the person knows to be false or misleading;

(e) in furnishing such information under paragraph (c), makes a statement which the person knows or ought to know to be false,

commits an offence and shall be liable, on conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding one year, or to both.

(2) A person who is convicted of an offence under subsection (1) shall be liable, for any subsequent offence, to a fine not exceeding two million shillings, or to imprisonment for a term not exceeding two years, or to both.

General penalty.

100. A person who commits an offence under this Act where a penalty is not provided shall be liable, on conviction, to a fine not exceeding ten million shillings or to imprisonment for a term not exceeding ten years, or to both.

PART X—TRANSITIONAL PROVISIONS

Transitional provisions.

101. (1) A person operating a health facility or providing healthcare services immediately before the commencement of this Act, shall, within six months of the commencement of this Act, comply with the requirements of this Act.

(2) All heath facilities registered before the commencement of this Act, shall be deemed to have been registered under this Act.

Consequential amendments.

102. The laws listed in the Second Schedule are amended in the manner specified in the Schedule.

FIRST SCHEDULE *(s.35)*
CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD

1. Meetings.

(1) The Board shall meet not less than four times in every financial year and not more than four months shall elapse between the date of one meeting and the date of the next meeting.

(2) The chairperson may call a special meeting of the Board at any time the chairperson deems fit for expedient transaction of the business of the Board.

(3) The notice for a meeting of the Board shall be given in writing to each member of the Board at least fourteen days before the day of the meeting.

(4) In the case of a special, or extra-ordinary meeting, a notice of less than fourteen days' notice shall be considered sufficient.

(5) Despite the provisions of subparagraph (2), the chairperson may, upon requisition in writing by at least two thirds of the members, convene a special meeting of the Board at any time for the transaction of the business of the Board.

(6) The notice to be given under subparagraph (2) and (3) shall state the—

(a) venue and time of the meeting; and
(b) agenda with sufficient details of business to be discussed at the meeting.

(7) The chairperson shall preside at every meeting of the Board at which the chairperson is present but in the chairperson's absence, the members present shall elect from among themselves a chairperson who shall, with respect to that meeting and the business transacted thereat, have all the powers of the chairperson.

(8) Unless a unanimous decision is reached, a decision on any matter before the Board shall be by the concurrence of a majority of all the members present and voting at the meeting.

(9) The Board may, with approval of the Cabinet Secretary, co-opt or invite any number of persons to act as advisors or consultants at any of its meetings or form such committees to perform such functions or duties of the Board as the Board shall determine.

(10) Subject to the provisions on quorum, no proceedings shall be invalid by reason only of a vacancy among the members of the Board.

(11) Subject to the provisions of this Schedule, the Board may determine its own procedure and the procedure for any committee of the Board.

(12) The quorum for the meetings of the Board shall be five members. Co-opted or invited persons shall not be counted in the quorum of the meetings of the Board and shall not be eligible to vote.

2. Contracts and instruments.

Any contract or instrument which, if entered into or executed by a person not being a body corporate, would not require to be under seal, may be entered into or executed on behalf of the Authority by any person generally or specially authorized by the Authority for that purpose.

3. Disclosure of Interest.

(1) If a member of the Board is present at a meeting of the Board or any committee at which any matter is the subject of consideration and in which matter that person is directly or indirectly interested in a private capacity, that person shall as soon as is practicable before the commencement of the meeting, declare such interest.

(2) The person making the disclosure of interest under paragraph (1) shall not, unless the Board or committee otherwise directs, take part in any consideration or, discussion of, or vote on any question touching on the matter.

(3) A person who contravenes subparagraph (1) commits an offence and shall be liable, on conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding six months, or to both.

(4) No member of the Board or officer, employee or agent of the Board shall enter into a service contract or trade with the Board.

(5) A disclosure of interest made under this paragraph shall be recorded in the minutes of the meeting at which it is made.

4. Minutes.
The Board shall cause minutes of all resolutions and proceedings of meetings of the Board to be entered in books kept for that purpose.

SECOND SCHEDULE *(s. 102)*
CONSEQUENTIAL AMENDMENTS TO OTHER ACTS

Amendment of section 2 of Cap. 241.

1. Section 2 of the Health Act is amended by—

(a) deleting the definition of the term "healthcare provider" and substituting therefor the following new definition—

"health care provider" means a person that delivers health care services;

(b) deleting the definition of the term "healthcare services" and substituting therefor the following new definition—

"healthcare services" means the prevention, promotion, education, medical diagnosis, management or alleviation of disease, illness, injury, and other physical and mental impairments in individuals, delivered by healthcare professionals through the health care system's routine health services including mortuaries, funeral homes and parlours, home care centres or its emergency medical care services;

(c) deleting the definition of the term "health facility" and substituting therefor the following new definition—

"health facility" means a person or an entity whether operating from a fixed physical structure or through mobile and digital platforms, that is established for the purpose of providing healthcare services, including hospitals, clinics, pharmacies, medical laboratories, mortuaries, funeral homes and parlours, home care centres, ambulances, mobile medical units, telemedicine services, medical aesthetic

procedures and community health services.

Amendment of section 14 of Cap. 241.

2. Section 14 of the Health Act is amended by deleting subsection (5) and substituting with the following new subsection—

"(5) Where a health facility fails to resolve a complaint to the satisfaction of the complainant, the Quality Health Care and Patient Safety Authority established under the Quality Healthcare and Patient Safety Act shall take the necessary action."

Amendment of section 48 of Cap. 241.

3. Section 48 of the Health Act is amended in subsection (1) by—

(a) deleting paragraph (b);

(b) deleting paragraph (c); and

(c) deleting paragraph (d).

Amendment of section 75 of Cap. 241.

4. Section 75 of the Health Act is amended in subsection (4) by deleting the words "regulatory body" and substituting therefor the words "Quality Health Care and Patient Safety Authority established under the Quality Healthcare and Patient Safety Act".

Amendment of section 89 of Cap. 241.

5. Section 89 of the Health Act is amended in—

(a) subsection (1), by deleting the words "appropriate regulatory bodies" and substituting therefor the words "Quality Health Care and Patient Safety Authority established under the Quality Healthcare and Patient Safety Act"; and

(b) subsection (2), by deleting the words "under this Act".

Amendment of section 91 of Cap. 241.

6. Section 91 of the Health Act is amended in subsection (1) by deleting the words "Authority and regulatory bodies" appearing in paragraph (a) and substituting therefor the words "Quality Health Care and Patient Safety Authority established under the Quality Healthcare and Patient Safety Act"

Amendment of section 3A of Cap. 244.

7. Section 3A of the Pharmacy and Poisons Act is amended in paragraph (e), by deleting the word "retailers" appearing immediately after the word "wholesalers".

Amendment of section 3B of Cap. 244.

8. Section 3B of the Pharmacy and Poisons Act is amended in subsection (2) by—

(a) deleting paragraph (c);

(b) deleting paragraph (f);

(c) deleting paragraph (i); and

(d) deleting paragraph (j).

Repeal of section 23 of Cap. 244.

9. The Pharmacy and Poisons Act is amended by repealing section 23.

Repeal of section 23A of Cap. 244.

10. The Pharmacy and Poisons Act is amended by repealing section 23A.

Amendment of section 2 of Cap. 246A.

11. Section 2 of the HIV and AIDS Prevention and Control Act is amended by deleting the definition of the term "tribunal" and substituting therefor the following new definition—

"tribunal" means the Health Care Tribunal established under section 86 of the Quality Health Care and Patient Safety Act.

Repeal of the heading of Part

12. The HIV and AIDS Prevention and Control Act is amended by repealing the heading of PART VII.

VII of Cap. 246A.

Repeal of section 25 of Cap. 246A.

13. The HIV and AIDS Prevention and Control Act is amended by repealing section 25.

Repeal of section 26 of Cap. 246A.

14. The HIV and AIDS Prevention and Control Act is amended by repealing section 26.

Repeal of section 27 of Cap. 246A.

15. The HIV and AIDS Prevention and Control Act is amended by repealing section 27.

Repeal of section 28 of Cap. 246A.

16. The HIV and AIDS Prevention and Control Act is amended by repealing section 28.

Repeal of section 29 of Cap. 246A.

17. The HIV and AIDS Prevention and Control Act is amended by repealing section 29.

Repeal of section 30 of Cap. 246A.

18. The HIV and AIDS Prevention and Control Act is amended by repealing section 30.

Amendment of section 2 of Cap. 253.

19. Section 2 of the Medical Practitioners and Dentists Act is amended—

(a) by deleting the definition of the term "health institution"; and

(b) in the definition of the term "private practitioner" by deleting the expression "section 15" and substituting therefor the words "the Quality of Health Care and Patient Safety Act".

Amendment of section 4 of Cap. 253.

20. Section 4 of the Medical Practitioners and Dentists Act is amended by—

(c) deleting paragraph (f);

(d) deleting paragraph (k);

(e) deleting paragraph (l);

(f) deleting paragraph (m); and

(g) deleting the words "and health institutions" appearing in paragraph (o).

Amendment of section 4A of Cap. 253.

21. Section 4A of the Medical Practitioners and Dentists Act is amended in subsection (1) by deleting the word "inspections" appearing in paragraph (c).

Amendment of section 5 of Cap. 253.

22. Section 5 of the Medical Practitioners and Dentists Act is amended in subsection (3) by—

(a) deleting paragraph (g);

(b) deleting paragraph (h); and

(c) deleting paragraph (i);

Repeal of section 15 of Cap. 253.

23. The Medical Practitioners and Dentists Act is amended by repealing section 15.

Amendment of section 15A of Cap. 253.

24. Section 15A of the Medical Practitioners and Dentists Act is amended by deleting the words "and every health institution shall in each year insure the health institution against professional liability of its staff" appearing immediately after the word "cover".

Amendment of section 16 of Cap. 253.

25. Section 16 of the Medical Practitioners and Dentists Act is amended by deleting the words "or section 15" appearing immediately after the expression "section 13".

Amendment of section 17 of Cap. 253.

26. The Medical Practitioners and Dentists Act is amended by repealing section 17.

Amendment of section 20 of Cap. 253.

27. Section 20 of the Medical Practitioners and Dentists Act is amended in—

(a) subsection (6), by deleting paragraph (e);

(b) subsection (7), by deleting the words "or health institution" appearing immediately after the word "person"; and

(c) subsection (8), by deleting the words "or health institution" appearing immediately after the word "person".

Amendment of section 22 of Cap. 253.

28. Section 22 of the Medical Practitioners and Dentists Act is amended by—

(a) deleting subsection (4); and

(b) deleting subsection (5).

Amendment of section 23 of Cap. 253.

29. Section 23 of the Medical Practitioners and Dentists Act is amended in paragraph (e) by deleting the words "or a health institution or the employee of a practitioner or health institution" appearing immediately after the words "incurred by a practitioner".

Amendment of section 5 of Cap. 253A.

30. Section 5 of the Medical Laboratory Technicians and Technologists Act is amended in—

(a) subsection (1) by deleting the words "business, practice" appearing immediately after the word "training"; and

(b) subsection (2) by—

(i) deleting paragraph (c); and

(ii) deleting paragraph (d).

Repeal of section 25 of Cap. 253A.

31. The Medical Laboratory Technicians and Technologists Act is amended by repealing section 25.

Amendment of section 40 of Cap. 253A.

32. Section 40 of the Medical Laboratory Technicians and Technologists Act is amended by—

(a) deleting paragraph (d); and

(b) deleting paragraph (g).

Repeal of section 38 of Cap. 253C.

33. The Counsellors and Psychologists Act is amended by repealing section 38.

Amendment of section 39 of Cap. 253D.

34. Section 39 of the Physiotherapist Act is amended in paragraph (g) by deleting the word "inspection".

Amendment of section 20 of Cap. 253E.

35. Section 20 of the Clinical Officers (Training, Registration and Licensing) Act is amended by—

(a) deleting subsection (5);

(b) deleting subsection (6);

(c) deleting subsection (7); and

(d) deleting subsection (8).

Repeal of section 23 of Cap. 253E.

36. The Clinical Officers (Training, Registration and Licensing) Act is amended by repealing section 23.

Amendment of section 23A of Cap. 253E.

37. Section 23A of the Clinical Officers (Training, Registration and Licensing) Act is amended by deleting the words "and every health institution shall in each year insure the health institution against professional liability of its staff" appearing immediately after the word "cover".

Amendment of section 2 of No. 16 of 2023.

38. Section 2 of the Social Health Insurance Act is amended by—

(a) deleting the definition of the term "Dispute Resolution Tribunal"; and

(b) inserting the following new definition in its proper alphabetical sequence—

"tribunal" means the Health Care Tribunal established under section 86 of the Quality Health Care and Patient Safety Act.

Amendment of section 33 of No. 16 of 2023.

39. Section 33 of the Social Health Insurance Act is amended in subsection (5) by deleting the words "Dispute Resolution".

Repeal of the heading of Part VIII of No.16 of 2023.

40. The Social Health Insurance Act is amended by repealing the heading of PART VII.

Amendment of section 43 of No.16 of 2023.

41. Section 43 of the Social Health Insurance Act is amended in subsection (1) by deleting the words "Dispute Resolution".

Repeal of section 44 of No.16 of 2023.

42. The Social Health Insurance Act is amended by repealing section 44.

Repeal of section 45 of No.16 of 2023.

43. The Social Health Insurance Act is amended by repealing section 45.

MEMORANDUM OF OBJECTS AND REASONS

The principal object of this Bill is to establish a comprehensive legal framework to promote the improvement of the quality of healthcare in Kenya by establishing standards, accreditation mechanisms and ensuring the protection and promotion of patient rights. The Bill therefore institutionalizes quality health care standards, accreditation mechanisms, and patient rights in Kenya for purposes of improving health outcomes, enhancing accountability in health systems and aligning the existing frameworks with global best practices.

Part I (clause 1 to 6) provides for preliminary matters including the short title, the objects of the Act and guiding principles on the implementation of the law when it becomes operational. It further provides various definitions such as quality of healthcare and accreditation for quality of healthcare among others. It sets out the role of the Cabinet Secretary responsible for health as well as those of the county governments in implementation of the Act.

Part II (clause 7 to 26) outlines the rights of patients who seek healthcare services from a health facility. These rights are to be read with those provided for under the Health Act, Cap. 241. The rights include right to safe and quality care, right to timely and effective care, right to safe and accessible health facilities, right to safe processes and practices, right to care by a qualified health professional, right to dignity and equity, right to information and decision making, right to informed consent, right to be heard and right to safe and quality health products and technologies.

Part III (clause 27 to 43) provides for the establishment of the Authority as the primary regulator of health facilities for purposes of quality of healthcare, its functions, powers; the composition, term of office, functions and qualifications of the Board of Directors of the Authority. It further provides for the appointment of a Chief Executive Officer and the staff of the Authority.

Part IV (clause 44 to 73) provides for the process of registration, licensing and accreditation of health facilities including timelines and prerequisites for grant of certificates for registration, licencing and accreditation, the validity period and instances where the Authority can order suspension or revocation of the certificates. It also provides for consequences of operating health facilities which are not registered or licenced. It sets out the quality improvement in a health facility, the procedure for quality scoring and rating, award of performance rating and monitoring of compliance by the Authority.

Part V (clause 74 to 84) provides for the conduct of inspections and investigations by the Authority including the qualifications and powers of inspectors.

Part VI (clause 85 to 87) provides for the establishment of a Health Care Tribunal, its composition and its role in adjudicating disputes arising out of matters envisaged by the Bill and the administration and enforcement of disputes in the health sector once it is enacted.

Part VII (clause 88 to 93) provides the sources of funds of the Authority, the modalities on annual reporting by the Authority and handling of the accounts of the Authority including the audit of its finances.

Part VIII (clause 94 to 100) provides for the delegation of power to the Cabinet Secretary in the Ministry responsible for health, in consultation with the Board of Directors of the Authority, to make regulations for the better carrying into effect of the provisions of the Act and the general provisions such as categorization of ambulances, right of review of a decision and appeal, offences and penalties.

Part IX (clause 101 to 102) provides for the transitional provisions in relation to the existing health facilities that provide healthcare services as well as consequential amendments to other statutes in light of the introduction of this Bill

The **First Schedule of the Bill** provides for the conduct of the business and affairs of the Board of the Authority.

The **Second Schedule of the Bill** provides the consequential amendments.