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Annex 3:

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILLS, NO.41 OF 2025)



REPUBLIC OF KENYA

PARLIAMENT

NATIONAL ASSEMBLY BILLS
(*Bill No. 41 of 2025*)

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL,2025

(A Bill published in the Kenya Gazette Supplement No. 144 of 2025 and passed by the National Assembly, with amendments, on Tuesday, 2nd June, 2026)

N.A. /B/No. 41/2025

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

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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 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 provide for the setting of standards for quality 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 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 26;

"Board" means the Board of Directors of the Authority appointed under section 29;

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

"Chief Executive Officer" means the Chief Executive Officer of the Authority appointed under section 35;

"clinical guidelines" means evidence-based guidelines developed and published by the Director-General for the delivery of healthcare services under section 20;

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

"emergency medical treatment" 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.

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

"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-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 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 Healthcare Tribunal established under section 83.

Objects of the Act.

3. The objects of this Act are to—

(a) guarantee patient rights and patient safety;

(b) provide a framework for the setting of standards for healthcare services and health facilities;

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

(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 health care 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 including staffing norms and standards;

(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 a county government.

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;

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(h) ensure health facilities and community health services within the county comply with the national standards on quality 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 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 a patient.

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

Right to safe and accessible health facilities.

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

(2) Every health facility shall—

(a) implement the 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) enforce policies to prevent violence, abuse or neglect of patients; and

(e) 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 healthcare 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 healthcare 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;

(b) from healthcare providers licensed by the relevant regulatory bodies; and

(c) 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 safe and quality care.

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

(a) safe and dignified;

(b) appropriate to their clinical needs; and

(c) compliant with the quality 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.

12. (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 health care to prevent harm;

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

(c) timely referrals, where appropriate.

Right to safe processes and practices.

13. (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.

14. (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 the 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.

15. (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 socio-economic status; and

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

Right to be heard.

16. (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) In order to promote efficient redress of complaints, every health facility shall provide a mechanism, which shall provide for all the matters specified in the standardized template issued by the Authority under subsection (4), for patients to lodge a complaint.

(4) The Authority shall issue a standardized template of the internal dispute resolution mechanism for health facilities.

(5) The Authority shall update the standardized template issued under subsection (4) after every two years.

Patient rights charter.

17. (1) In order to promote awareness and quality healthcare, every health facility shall develop a patient rights charter which shall provide for all the matters specified in the standardized template issued by the Authority under subsection (3).

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

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

(4) The Authority shall update the standardized

template issued under subsection (3) after every two years.

Patient safety and quality assurance measures.

18. (1) A health facility shall—

(a) implement measures to ensure patient safety and quality 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;

(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;

(d) provide mechanisms for adherence to professional standards; and

(e) ensure compliance to training and internship standards and guidelines.

(2) A health facility which fails to comply with the provisions of this section commits an offence and shall be liable, on conviction, to a fine not exceeding ten million shillings.

Duty to uphold quality healthcare.

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

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

Evidence-based practice.

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

(2) The Director-General shall develop and publish clinical guidelines from time to time.

Safety and risk management.

21. (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

No. 15 of 2023.

Integrated Health Information System established under the Digital Health Act;

(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, where the healthcare provider has provided a healthcare service, any act, omission or circumstance that may pose a risk to patient safety within the heath facility.

(4) The Authority shall issue a standardized template for use by healthcare providers to report to the health facility any act, omission or circumstance that may pose a risk to patient safety.

(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.

(6) The Authority shall update the standardized template issued under subsection (4) after every two years.

Quality improvement.

22. (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 treatment; 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.

23. Every county government and health facility shall—

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

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

Professional indemnity.

24. (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.

25. Every patient shall—

(a) adhere to the rules of a health facility when receiving treatment or using the healthcare services provided at a health facility;

(b) adhere to the medical advice and treatment provided by a health facility or healthcare provider;

(c) supply the healthcare provider with accurate information pertaining to the patient's health status;

(d) cooperate with the healthcare provider;

(e) treat healthcare providers and healthcare workers with dignity and respect; and

(f) if so requested, sign a discharge certificate or release of liability if the patient refuses to accept or implement recommended treatment.

PART III—ADMINISTRATION OF QUALITY HEALTHCARE

Establishment of the Authority.

26. (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.

(3) The Headquarters of the Authority shall be in Nairobi but the Authority shall ensure access to its services in all parts of the Republic in accordance with Article 6 (3) of the Constitution.

Functions of the Authority.

27. The functions of the Authority shall be to—

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

(b) register, license and accredit health facilities;

(c) regulate the conduct of health facilities;

(d) enforce compliance with quality healthcare standards;

(e) inspect health facilities for compliance with the quality healthcare standards;

(f) undertake or cause to be undertaken, regular inspections, monitoring and evaluation of health facilities to ensure compliance with the provisions of this Act;

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

(h) accredit health facilities for purposes of empanelment and contracting under section 33 and 34 of the Social Health Insurance Act; No. 16 of 2023.

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

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

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

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

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

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

Powers of the Board.

28. (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) Without prejudice to subsection (1), the Board shall have the power to—

(a) manage, control and administer the assets of the Authority in accordance with the Public Procurement and Asset Disposal Act; Cap. 412C.

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

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

(d) 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;

(e) 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;

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

(g) 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

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

Board of Directors of the Authority.

29. (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 healthcare standards or a representative designated in writing;

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

(d) the Attorney-General or a representative designated in writing;

(e) the Director-General;

(f) 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 in the health sector;

(g) one person appointed by the Cabinet Secretary, not being a public officer, nominated by healthcare providers;

(h) one person nominated by consumer rights bodies in the health sector, appointed by the Cabinet Secretary to represent the public interest;

(i) one person nominated by statutory regulatory bodies in the health sector and appointed by the Cabinet Secretary; and

(j) 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)(f), (g), (h) and (i) shall be by notice in the *Gazette*.

Qualification for appointment as Chairperson or Member of the Board.

30. (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 healthcare sciences from a university recognized in Kenya;

(c) has professional practice, knowledge and experience of at least ten years in health governance, leadership, health administration or public policy;

(d) has served in a senior management level for a period of at least five 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 29(1)(f), (g), (h) and (i) 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, healthcare sciences, health administration and management or quality management and improvement; and

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

Term of office.

31. (1) The chairperson and the members appointed under section 29 (1)(f), (g), (h) and (i) 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 29 (1) (b), (c), (d) and (e) shall hold office during their tenure of office unless removed from office by the appointing authority.

Committees of the Board.

32. (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.

33. (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.

34. 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.

35. (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 healthcare sciences from a university recognized in Kenya;

(c) is a registered member of a healthcare 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

36. (1) The Chief Executive Officer may be removed

from office by the Board in accordance with the terms and condition of service, for— office of the Chief Executive Officer.

(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 and sentenced 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.

37. (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. Corporation Secretary.

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

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

(3) The Corporation Secretary shall be the Secretary to the Board and shall—

(a) in consultation with the Chairperson of the Board, issue notices for the meetings of the Board;

(b) take minutes of the meetings of the Board;

(c) keep, in custody, the records of the deliberations, decisions and resolutions of the Board;

(d) transmit the decisions and resolutions of the Board to the Chief Executive Officer for execution, implementation and other relevant action;

(e) provide guidance on legal compliance and governance matters to the Board;

(f) provide guidance to the Board on its duties and responsibilities on matters relating to governance; and

(g) perform such other duties as the Board may direct.

Staff of the Authority.

38. 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.

Remuneration.

39. 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.

40. (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 acts committed by the member of the Board, officer, employee or agent of the Authority.

Common seal.

41. (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.

42. (1) A person who intends to construct or operate a health facility shall obtain approval from the Authority before commencing the construction or operation.

(2) The Cabinet Secretary shall prescribe the requirements for—

(a) health facilities;

(b) ambulances;

(c) medical camps; and

(d) such other health facility as may be prescribed by the Cabinet Secretary.

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

(4) The Authority may, in collaboration with the relevant government agencies, develop frameworks for the purposes of assessing the approval process of health facilities.

(5) A person who intends to decommission a health facility shall obtain approval from the Authority before

the decommissioning.

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

Registration of a health facility.

43. (1) A person who intends to operate a health facility shall, after acquiring approval under section 42 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.

44. (1) An application for registration of a health facility shall be made in the prescribed form and be accompanied by—

(a) the approval issued under section 42;

(b) such description of a health facility specific information or activity as may be prescribed by the Cabinet Secretary;

(c) the prescribed fee;

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

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

(f) 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.

45. (1) Where the Authority is satisfied 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.

46. (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 require the health facility to furnish reasons why the licence should not be suspended, within fourteen days of service of the notice.

(3) A person aggrieved by the decision of the Authority under this section may, within twenty-one days from the day of the notification under subsection (2) lodge an appeal before the Tribunal.

(4) 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.

47. (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 or any other relevant laws; and

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

(2) Where the Authority intends to revoke a certificate of registration under this section, it may, at least twenty-one days before the date of the intended revocation, notify the health facility of such intention, specifying the reasons thereof and shall require the health facility to furnish reasons why the certificate of registration should not be suspended, within fourteen days of service of the notice.

(3) A person aggrieved by the decision of the Authority under this section may, within twenty-one days from the day of the notification under subsection (1) lodge an appeal before the Tribunal.

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

Licence.

48. (1) A health facility issued with a certificate of registration by the Authority under section 45 shall 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 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.

49. An application for a licence shall be in the prescribed form and be accompanied by—

(a) a copy of the approval issued under section 42;

(b) a copy of a certificate of registration issued under section 45;

(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 the 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.

50. 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 health facility as set out in the First Schedule to the Health Act and

the Regulations prescribed by the Cabinet Secretary under this Act; Cap. 241.

(b) the healthcare providers providing services at the health facility are holders of valid practicing 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 health care to be provided at the health facility complies with the quality healthcare standards prescribed under this Act.

Validity of the licence.

51. 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 upon the licensee making an application for renewal.

Categorization of health facilities.

52. (1) For purposes of licensing under this Act, the Authority shall categorize registered health facilities in accordance with the First Schedule to the Health Act and the Regulations prescribed by the Cabinet Secretary. Cap. 241.

(2) Notwithstanding subsection (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.

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

Services offered by health facilities.

53. (1) A licence issued to a health facility shall specify the nature of the 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 treatment 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.

54. (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 intends to suspend a licence under this section, it may, at least twenty-one days before the date of the intended suspension, notify the health facility of the intention, specifying the reasons thereof and require the health facility to furnish reasons why the licence should not be suspended, within fourteen days of service of the notice.

(3) 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.

(4) A person aggrieved by the decision of the Authority under this section may, within twenty-one days from the day of the notification under subsection (1) lodge an appeal before the Tribunal.

Revocation of a licence.

55. (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 intends to revoke a licence under subsection (1), the Authority shall serve the health

facility with a notice of the intended revocation specifying the grounds for such revocation and shall require the health facility to, within fourteen days of service of the notice, furnish reasons why the licence should not be revoked.

(3) Where the health facility fails to give reasons within the specified period under subsection (2), the Authority shall revoke the licence..

(4) If the health facility furnishes reasons, the Authority shall after considering the reasons decide on whether or not to revoke the licence.

(5) 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 healthcare.

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

Role of the Authority in accreditation for quality healthcare.

57. (1) The Authority shall accredit a health facility registered and licensed under this Act for quality healthcare in accordance with the quality healthcare standards prescribed by the Cabinet Secretary.

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

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

(b) appoint quality assessors to conduct the accreditation of health facilities;

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

(d) publicize and disseminate the quality 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 healthcare standards.

Application for accreditation.

58. (1) A person shall apply to the Authority for accreditation of a health facility under 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 using the template developed under subsection (3).

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

(4) The Authority shall update the template developed under subsection (3) after every two years.

(5) 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.

(6) 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.

(7) 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.

59. The Authority shall accredit a health facility, based on —

(a) compliance with the applicable quality healthcare standards;

(b) conformity to infrastructure standards;

(c) conformity to human resource requirements;

(d) conformity with disease-specific clinical guidelines;

(e) conformity to health products and technology standards;

(f) the monitoring of patient outcomes;

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

(h) such other criteria as may be prescribed by the Cabinet Secretary.

Certificate of accreditation.

60. 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.

61. 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.

62. 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.

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

(a) health facility fails to meet the quality 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 Authority intends to suspend the accreditation of a health facility 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 require the health facility to furnish reasons why the accreditation should not be suspended, within fourteen days of service of the notice.

(3) Where the accreditation of a health facility is suspended under subsection (1), the Authority shall publish the suspension in the *Gazette*.

(4) A person aggrieved by the decision of the Authority under this section may, within twenty-one days from the day of the notification of suspension lodge an appeal before the Tribunal.

Revocation of accreditation.

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

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

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

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

(2) Where the accreditation of a health facility is revoked under subsection (1), the Authority shall publish in the *Gazette* as soon as may be practicable the name of the health facility whose accreditation is revoked.

(3) A person aggrieved by the decision of the Authority under this section may, within twenty-one days from the day of the notification of revocation lodge an appeal before the Tribunal.

Quality improvement in a health facility.

65. 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.

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

(4) The Authority shall publish in the *Gazette* the results of the quality assessment and quality rating of licensed health facilities.

Award of a performance rating.

67. (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 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.

68. Where a health facility is found to be non-compliant with the quality healthcare standards, the Authority shall take 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 the quality healthcare standards or failure to submit required reports;

(d) suspending or revoking accreditation where the health facility fails to comply with the quality 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.

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

Register of health facilities.

70. (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) 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.

(5) 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.

71. (1) The Chief Executive Officer may for a specified duration and on the recommendations of the Board, 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 of quality 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.

(3) 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.

PART V—INSPECTIONS, INVESTIGATIONS AND ENFORCEMENT

Appointment of health facility inspectors.

72. (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.

73. (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.

74. An inspector appointed under this Act may—

(a) inspect a health facility for purposes of registration and licensing;

(b) enter, inspect and search any health facility which the inspector has reason to believe that--

(i) the inspection is necessary in order to ascertain whether the provisions of this Act are being

complied with, or

(ii) an offence is being committed or is suspected to have been committed;

(c) take any equipment or material required for any purpose for which 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 the 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.

Qualifications of inspectors.

75. The Authority shall, by Gazette Notice, appoint duly qualified persons, to be inspectors of the Authority for the purposes of this Act.

Conduct of inspections.

76. (1) 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 or licensing due to non-compliance with the quality 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.

77. (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.

78. (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, aircraft or other means of conveyance that the Authority or the inspector is empowered to enter under this Act or Regulations made there under;

(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.

79. (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 and Regulations.

(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 which 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.

80. (1) Upon receipt of an inspection report under section 79 (3), the Authority shall—

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

(b) ensure that relevant measures have been taken against the persons contravening the provisions of this 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) A person subject to the enforcement action shall take the necessary measures to—

(a) remedy compliance as directed by the Authority as soon as it is 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.

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

Inspection of records.

82. (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 fails 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—HEALTHCARE TRIBUNAL

Establishment of the Health Care Tribunal.

83. (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.

(2) The Tribunal shall consist of—

(a) a Chairperson who shall be appointed by the Judicial Service Commission from among persons qualified to be judges of the High Court;

(b) three advocates of the High Court of not less than ten years' standing appointed by the Judicial Service Commission;

(c) four senior healthcare professionals, not being public officers or employees of the Board with over ten years' experience who shall be appointed by the Judicial Service Commission; and

(d) three other persons who shall be appointed by the Judicial Service Commission and shall possess knowledge and experience in matters of policy, human resource and quality improvement and who are not public officers or employees of the Board and are not health service providers.

(3) 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.

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

(5) The members of the Tribunal shall be entitled to receive such allowances as the Judicial Service Commission, on the advice of the Salaries and Remuneration Commission, may determine.

(6) The Chief Justice shall make rules for the operationalization of the Tribunal.

Jurisdiction of the Tribunal.

84. (1) The Tribunal shall have jurisdiction to hear and determine all matters referred to it, relating to the health sector arising under this Act.

(2) The jurisdiction of the Tribunal shall not include the trial of any criminal offence.

(3) The Tribunal shall have original jurisdiction on any dispute relating to health facilities and patients.

(4) The Tribunal shall have appellate jurisdiction over the decisions of the Authority and any relevant regulatory body in the health sector and in exercise of its functions, may refer any matter back to the Authority and any relevant regulatory body in the health sector for re-consideration.

(5) The Tribunal shall have power to grant equitable reliefs including but not limited to injunctions, penalties, damages and specific performance.

(6) The Tribunal shall hear and determine matters referred to it expeditiously.

Appeals to the Tribunal.

85. (1) A person aggrieved by a decision or action made under this Act may, within twenty-one 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 thirty days from the date the order is made.

Vacancy in the Tribunal.

86. 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.

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

(d) 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.

88. (1) The Authority may invest monies which are not immediately required in accordance with the Public Finance Management Act.

Cap. 412A

Financial year.

89. 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.

90. (1) The Board 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.

91. (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.

92. (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 VIII— PROVISIONS ON DELEGATED POWERS

Regulations.

93. (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 Regulations may prescribe—

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

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

(c) the procedure for registration and licensing of health facilities;

(d) the procedure for approval, review and assessment of health facilities;

(e) the manner of conducting inspections;

(f) standards of community health services;

(g) standards of medical laboratories;

(h) standards of pharmacies;

(i) standards of ambulance services;

(j) standards of emergency medical treatment;

(k) standards of telemedicine services;

(l) standards of alternative medicine and traditional medicine;

(m) standards of medical aesthetic procedures;

(n) the procedure for accreditation of health facilities for quality healthcare ;

(o) conduct of inspections;

(p) investigation procedures;

(q) quality healthcare standards;

(r) categories of health facilities;

(s) quality rating;

(t) administrative fines for failure to comply with the requirements of this Act; and

(u) any other matter that may be related to quality healthcare.

(3) For the purposes of Article 94(6) of the Constitution—

(a) the power of the Cabinet Secretary to make regulations shall be limited to bringing into effect the provisions of this Act and the fulfilment of the objectives specified under subsection (1); and

(b) the principles and standards set out under the Statutory Instruments Act and the Interpretation and General Provisions Act in relation to subsidiary legislation shall apply to Regulations made under this Act.

Cap. 2A.
Cap.2

PART IX— GENERAL PROVISIONS

Review.

94. (1) A person aggrieved by a decision of the Authority under this Act may apply to the Authority for a review of the decision within thirty days of receipt of the decision.

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

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

Appeals.

95. 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.

96. 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.

97. (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;

(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; or

(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.

98. 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.

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

(2) A person operating a health facility or providing healthcare services immediately before the commencement of this Act, shall be required to comply with the requirements of this Act and apply for registration of the health facility under this Act within one year after the commencement of this Act.

(3) The Cabinet Secretary may by notice in the *Gazette* extend the period of registration specified in subsection (1).

(4) A person who, immediately before the commencement of this Act was an employee or a member of staff of the Kenya Medical Practitioners and Dentists Council or any relevant regulatory body handling matters pertaining to the regulation of health facilities, not being then under notice of dismissal or resignation shall, on the commencement of this Act, be deemed to be an employee or member of the staff of the Authority on the same terms and conditions.

Consequential amendments.

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

FIRST SCHEDULE *(s.33)*

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 the 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' 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 the 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 the 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. 100)

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 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 mental health services, alternative medicine and traditional medicine, medical aesthetic procedures, community health services, telemedicine services or its emergency health services;

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

"health facility" means an institution 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, and community outreach programs;

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 20 of Cap. 241.

3. Section 20 of the Health Act is amended in—

(a) paragraph (d) by deleting the words "national

government department responsible for health and relevant 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) paragraph (i) by deleting the words "national government department responsible for health, the Authority and professional regulatory bodies established under any written law" and substituting therefor the words "Quality Health Care and Patient Safety Authority established under the Quality Healthcare and Patient Safety Act".

Amendment of section 48 of Cap. 241.

4. Section 48 of the Health Act is amended—

(a) in subsection (1) by inserting the words ",in relation to the regulation of healthcare professionals," immediately after the word "Authority"; and

(b) in subsection (2) by inserting the words ",in relation to the regulation of healthcare professionals" immediately after the word "prescribe".

Amendment of section 60 of Cap. 241.

5. Section 60 of the Health Act is amended in subsection (1) by deleting the words "The obligation to inspect, monitor and evaluate the standard of performance in all the services regulated and" and substituting therefor the words "The obligation to monitor and evaluate the conduct of".

Amendment of section 80 of Cap. 241.

6. Section 80 of the Health Act is amended by deleting subsection (3).

Amendment of section 89 of Cap. 241.

7. 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 112 of Cap. 241.

8. Section 112 of the Health Act is amended by—

(a) deleting paragraph (a);

(b) deleting paragraph (b);

(c) deleting paragrah(c);

(d) deleting paragraph (e);

(e) deleting paragraph (p); and

(f) deleting paragraph (r);

Repeal of section 153 of Cap. 242.

9. The Public Health Act is amended by repealing section 153.

Amendment of section 3B of Cap. 244.

10. Section 3B of the Pharmacy and Poisons Act is amended in—

(a) subsection (2) by deleting the words "pharmacies, including those in hospitals and clinics, and other retail outlets" appearing in paragraph (j); and

(b) subsection (3), by deleting paragraph (i).

Amendment of section 14 of Cap. 244

11. Section 14 of the Pharmacy and Poisons Act is amended in—

(a) subsection (1), by deleting the term "Supreme Court" and substituting therefor the term "High Court"; and

(b) subsection (2), by deleting the term "Supreme Court" wherever it appears and substituting therefor the term "High Court".

Amendment of section 15 of Cap. 244

12. Section 15 of the Pharmacy and Poisons Act is amended by deleting the term "Supreme Court" and substituting therefor the term "High Court".

Amendment of section 16 of Cap. 244

13. Section 16 of the Pharmacy and Poisons Act is amended by deleting the term "Supreme Court" and substituting therefor the term "High Court".

Repeal of section 23 of Cap. 244.

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

Repeal of section 23A of Cap. 244.

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

Amendment of section 44 of Cap. 244.

16. Section 44 of the Pharmacy and Poisons Act is amended in subsection (1) by deleting paragraph (mb).

Amendment of section 9B of Cap. 248.

17. Section 9B of the Mental Health Act is amended in subsection (1) by deleting the words "relevant medical

regulatory body" and substituting therefor the words "Quality Healthcare and Patient Safety Authority established under the Quality Healthcare and Patient Safety Act".

Repeal of section 9C of Cap. 248.

18. The Mental Health Act is amended by repealing section 9C.

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";

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

(c) in definition of the term "register", by deleting the words "and health institutions for public and private practice".

Amendment of section 4 of Cap. 253.

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

(a) deleting paragraph (k);

(b) deleting paragraph (l);

(c) deleting paragraph (m); and

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

Amendment of section 5 of Cap. 253.

21. Section 5 of the Medical Practitioners and Dentists Act is amended in subsection (3) by deleting paragraph (i).

Repeal of section 15 of Cap. 253.

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

Amendment of section 15A of Cap. 253.

23. 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.

24. 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.

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

Amendment of section 20 of Cap. 253.

26. 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.

27. 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.

28. 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.

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

(a) subsection (1), by deleting the word "business," and substituting therefor the word "professional"; and

(b) subsection (2), by deleting the word "the business and" appearing in paragraph (d) and substituting therefor the word "professional".

Amendment of the heading of Part IV of Cap. 253A.

30. The Medical Laboratory Technicians and Technologists Act is amended in the heading of PART IV by deleting the word "PRIVATE" and substituting therefor the word "PROFESSIONAL".

Amendment of section 20 of Cap. 253A.

31. Section 20 of the Medical Laboratory Technicians and Technologists Act is amended—

(a) in the marginal note by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (1) by deleting the word "private" and substituting therefor the word "professional"; and

(c) in subsection (3), by deleting the word "private" and substituting therefor the word "professional".

Amendment of section 22 of Cap. 253A.

32. Section 22 of the Medical Laboratory Technicians and Technologists Act is amended by—

(a) deleting the words "and place of business" appearing in subsection (1); and

(b) inserting the word "professional" immediately after the words "suspended from" appearing in subsection (3).

Amendment of section 25 of Cap. 253A.

33. Section 25 of the Medical Laboratory Technicians and Technologists Act is amended—

(a) in the marginal note by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (1) by deleting the words "business and practice of laboratory technicians and technologists engaged in private practice" and substituting therefor the words "professional practice of laboratory technicians and technologists"; and

(c) by deleting subsection (2) and substituting therefor the following new subsection—

"(2) Regulations under subsection (1) shall in particular provide for the services to be rendered by laboratory technicians and technologists in their professional practice".

Amendment of section 40 of Cap. 253A.

34. Section 40 of the Medical Laboratory Technicians and Technologists Act is amended by deleting paragraph (g).

Amendment of section 2 of Cap. 253B.

35. Section 2 of the Nutritionists and Dieticians Act is amended by deleting the definition of the term "health institution" and substituting therefor the following new definition—

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

Amendment of section 22 of Cap. 253B.

36. Section 22 of the Nutritionists and Dieticians Act is amended —

(a) in subsection (1), by deleting the word "private" appearing immediately after the words "engage in" and substituting therefor the word "professional";

(b) in subsection (2), by deleting the words "on his or her own behalf or to be employed by a registered

nutritionist or dietician"; and

(c) in subsection (3), by deleting the words "and shall state whether the licensee may practise on his own behalf or on employment".

Amendment of the Long Title of Cap. 253C.

37. The Long Title of the Counsellors and Psychologists Act is amended by inserting the word "professional" immediately after the word "licensing".

Amendment of section 6 of Cap. 253C.

38. Section 6 of the Counsellors and Psychologists Act is amended in—

(a) paragraph (ja), by inserting the word "professional" immediately after the words "matters related to the"; and

(b) paragraph (k), by inserting the word "professional" immediately after the words "conditions of".

Amendment of the Long Title of Cap. 253D.

39. The Long Title of the Physiotherapists Act is amended by inserting the word "professional" immediately after the words "to regulate their".

Amendment of section 2 of Cap. 253D.

40. Section 2 of the Physiotherapists Act is amended by inserting the following new definition in its proper alphabetical sequence—

"practicing certificate" means a certificate issued to a professional registered under this Act.

Amendment of section 4 of Cap. 253D.

41. Section 4 of the Physiotherapists Act is amended in—

(a) subsection (1), by inserting the word "professional" immediately after the words "training and"; and

(b) subsection (2), by deleting the word "private" appearing in paragraph (f) and substituting therefor the word "professional".

Amendment of the heading of Part V of Cap. 253D.

42. The Physiotherapists Act is amended in the heading of PART V by deleting the word "PRIVATE" and substituting therefor the word "PROFESSIONAL".

Amendment of section 24 of Cap. 253D.

43. Section 24 of the Physiotherapists Act is amended—

(a) in the marginal note by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (1), by deleting the word "private" and substituting therefor the word "professional";

(c) in subsection (2), by deleting the words "private practice" wherever they appear and substituting therefor the words "professional practice"; and

(d) in subsection (3), by deleting the word "private" and substituting therefor the word "professional".

Amendment of section 39 of Cap. 253D.

44. Section 39 of the Physiotherapists Act is amended in subsection (2) by—

(a) inserting the words "of approved training institutions" immediately after the word 'inspection" appearing in paragraph (g);

(b) deleting paragraph (h) and substituting therefor the following new paragraph (h)—

"(h) prescribe the terms and conditions of the professional practice of physiotherapists including the services to be rendered by physiotherapists in professional practice"; and

(c) deleting paragraph (i) and substituting therefor the following new paragraph—

"(i) any other matter related to the professional practice of physiotherapists".

Amendment of the Long Title of Cap. 253E.

45. The Long Title of the Clinical Officers (Training, Registration and Licensing) Act is amended by inserting the word "professional" immediately after the words "to regulate their".

Amendment of section 2 of Cap. 253E.

46. Section 2 of the Clinical Officers (Training, Registration and Licensing) Act is amended—

(a) in the definition of the term "clinic" by deleting the words "Council" and substituting therefor the words "Quality Health Care and Patient Safety Authority";

(b) by deleting the definition of the term "medical centre"; and

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

"practicing licence" means a certificate issued to a professional registered under this Act.

Amendment of the heading of Part IV of Cap. 253E.

47. The Clinical Officers (Training, Registration and Licensing) Act is amended in the heading of PART IV by inserting the word "PROFESSIONAL" immediately after the words "LICENSING AND".

Amendment of

48. Section 20 of the Clinical Officers (Training,

section 20 of Cap. 253E.

Registration and Licensing) Act is amended—

(a) in the marginal note by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (1), by deleting the word "private" and substituting therefor the word "professional";

(c) in subsection (2) by deleting the word "private" and substituting therefor the word "professional";

(d) in subsection (3), by deleting the words "private practice" wherever they appear and substituting therefor the words "professional practice";

(e) in subsection (4), by deleting the word "private" and substituting therefor the word "professional";

(f) by deleting subsection (5);

(g) by deleting subsection (6);

(h) by deleting subsection (7); and

(i) by deleting subsection (8).

Amendment of section 21 of Cap. 253E.

49. Section 21 of the Clinical Officers (Training, Registration and Licensing) Act is amended in—

(a) subsection (1), by deleting the word "private"; and

(b) subsection (3), by deleting the word "certificate" and substituting therefor the word "licence".

Amendment of section 22 of Cap. 253E.

50. Section 22 of the Clinical Officers (Training, Registration and Licensing) Act is amended in subsection (1), by inserting the word "professional" immediately after the words "no person shall engage in the".

Amendment of section 23 of Cap. 253E.

51. Section 23 of the Clinical Officers (Training, Registration and Licensing) Act is amended —

(a) in the marginal note, by deleting the word "private" and substituting therefor the word "professional; and

(b) by deleting the words "business and practice of a clinical officer engaged in private practice" and substituting therefor the word "professional practice of clinical officers".

Amendment of section 23A of Cap. 253E.

52. 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 24 of Cap. 253E.

53. Section 24 of the Clinical Officers (Training, Registration and Licensing) Act is amended in subsection (3) by deleting paragraph (b).

Amendment of section 31 of Cap. 253E.

54. Section 31 of the Clinical Officers (Training, Registration and Licensing) Act is amended in subsection (2) by inserting the words "of approved training institutions" immediately after the word "inspection" appearing in paragraph (e).

Amendment of the Long Title of Cap. 253F.

55. The Long Title of the Radiographers Act is amended by inserting the word "professional" immediately after the words "to regulate their".

Amendment of section 4 of Cap. 253F.

56. Section 4 of the Radiographers Act is amended in—

(a) subsection (1), by inserting the word 'professional" immediately after the words "training and"; and

(b) subsection (2), by deleting paragraph (d).

Amendment of the heading of Part IV of Cap. 253F.

57. The Radiographers Act is amended in the heading of PART IV by deleting the word "PRIVATE" and substituting therefor the word "PROFESSIONAL".

Amendment of section 18 of Cap. 253F.

58. Section 18 of the Radiographers Act is amended—

(a) in the marginal note by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (1), by deleting the word "private" and substituting therefor the word "professional";

(c) in subsection (2), by deleting the words "private practice" wherever they appear and substituting therefor the words "professional practice"; and

(d) in subsection (3), by deleting the word "private" and substituting therefor the word "professional".

Amendment of section 39 of Cap. 253F.

59. Section 39 of the Radiographers Act is amended in subsection (2) by—

(a) inserting the words "of approved training institutions" immediately after the word 'inspection" appearing in paragraph (d); and

(b) deleting paragraph (e) and substituting therefor the following new paragraph—

"(e) the terms and conditions of the practice of a radiographer engaged in professional practice and the services to be rendered by a radiographer in professional practice".

Amendment of section 46 of Cap. 253G.

60. Section 46 of the Public Health Officers (Training, Registration and Licensing) Act is amended in paragraph (g) by inserting the words "as provided in the Public Health Act" immediately after the word "institutions".

Amendment of the Long Title of Cap. 253H.

61. The Long Title of the Occupational Therapists (Training, Registration and Licensing) Act is amended by inserting the word "professional" immediately after the words "to regulate their".

Amendment of section 2 of Cap. 253H.

62. Section 2 of the Occupational Therapists (Training, Registration and Licensing) Act is amended by inserting the following new definition in its proper alphabetical sequence—

"licence" means a licence issued to an occupational therapist registered under this Act.

Amendment of section 8 of Cap. 253H.

63. Section 8 of the Occupational Therapists (Training, Registration and Licensing) Act is amended by—

(a) deleting paragraph (c); and

(b) deleting paragraph (f).

Amendment of the heading of Part V of Cap. 253H.

64. The Occupational Therapists (Training, Registration and Licensing) Act is amended in the heading of PART IV by deleting the word "PRIVATE PRACTICE" and substituting therefor the word "LICENSING".

Amendment of section 28 of Cap. 253H.

65. Section 28 of the Occupational Therapists (Training, Registration and Licensing) Act is amended in—

(a) subsection (1) by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (2), by deleting the words "on his or her own behalf or to be employed by a registered occupational therapist";

(c) in subsection (3), by deleting the words "and shall state whether the licensee may practice on his own

behalf or on employment"; and

(d) subsection (4), by deleting the word "private" and substituting therefor the word "professional".

Amendment of section 29 of Cap.253H.

66. Section 29 of the Occupational Therapists (Training, Registration and Licensing) Act is amended in—

(a) the marginal note, by deleting the word "private" and substituting therefor the word "professional";

(b) subsection (1), —

(i) by inserting the word "professional" immediately after the words "not engage in";

(ii) by deleting the word "private" appearing in paragraph (c) and substituting therefor the word "professional"; and

(c) subsection (3), by deleting the word "private" and substituting therefor the word "professional".

Amendment of section 30 of Cap. 253H.

67. Section 30 of the Occupational Therapists (Training, Registration and Licensing) Act is amended in subsection (1) by inserting the word "professional" immediately after the words "engage in the".

Amendment of section 31 of Cap. 253H.

68. Section 31 of the Occupational Therapists (Training, Registration and Licensing) Act is amended —

(a) in the marginal note, by deleting the word "private" and substituting therefor the word "professional";

(b) in subsection (1), by deleting the word "private" and substituting therefor the word "professional"; and

(c) by deleting subsection (2) and substituting therefor the following new subsection—

"(2) Regulations made under subsection (1) shall in particular provide for the services to be rendered by an occupational therapist in professional practice."

Amendment of section 40 of Cap. 253H.

69. Section 40 of the Occupational Therapists (Training, Registration and Licensing) Act is amended in subsection (2) by deleting the words "private practice licence" appearing in paragraph (d).

Amendment of section 41 of Cap. 253H.

70. Section 41 of the Occupational Therapists (Training, Registration and Licensing) Act is amended by deleting the words "carry on business or".

Amendment of section 2 of Cap. 257.

71. Section 2 of the Nurses and Midwives Act is amended by deleting the definition of the term "health institution" and substituting therefor the following new definition—

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

Amendment of section 9 of Cap. 257.

72. Section 9 of the Nurses and Midwives Act is amended in subsection (1) by—

(a) deleting the words "and of health care within the community" appearing in paragraph (b); and

(b) deleting paragraph (i).

Amendment of section 17 of Cap. 257.

73. Section 17 of the Nurses and Midwives Act is amended—

(a) by deleting subsection (2);

(b) by deleting subsection (3);

(c) in subsection (4), by deleting the words "engage in private"; and

(d) in subsection (5), by deleting the words "engage in private".

Repeal of section 22 of Cap. 257.

74. The Nurses and Midwives Act is amended by repealing section 22.

Amendment of the Long Title of Cap. 539.

75. The Long Title of the Health Records and Information Managers Act is amended by inserting the word "professional" immediately after the words "regulate their".

Amendment of section 2 of Cap. 539.

76. Section 2 of the Health Records and Information Managers Act is amended by—

(a) deleting the term "health institution" and substituting therefor the following new definition—

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

(b) deleting the words "facility in a health institution" appearing in the definition of the term "health records and information management department" and substituting therefor the words "health facility";

(c) deleting the definition of the word "private practice"; and

(d) deleting the definition of the word "private practitioner".

Amendment of section 21 of Cap. 539.

77. Section 21 of the Health Records and Information Managers Act is amended by—

(a) deleting subsection (3); and

(b) deleting subsection (4).

Amendment of the heading of Part IV of Cap. 539.

78. The Health Records and Information Managers Act is amended in the heading of Part IV by deleting the words "PRIVATE PRACTICE AND".

Amendment of section 24 of Cap. 539.

79. Section 24 of the Health Records and Information Managers Act is amended —

(a) by deleting the marginal note and substituting therefor the following new marginal note—

"24. Licence to practice";

(b) in subsection (1), by deleting the word "private";

(c) deleting subsection (6); and

(d) deleting subsection (7).

I certify that this printed impression is a true copy of the Bill passed by the National Assembly on the 2nd June, 2026.

Clerk of the National Assembly

Endorsed for presentation to the Senate in accordance with the provisions of Standing Order 142 of the National Assembly Standing Orders.

Speaker of the National Assembly

PARLIAMENT OF KENYA
THE SENATE
SENATE BILLS DIGEST

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILLS NO. 41 OF 2025)

Sponsor:	The Leader of the Majority Party, National Assembly, and Leader of Majority Party, Senate.
Date of Publication:	17th July, 2025.
Date of First Reading (Senate):	15th July, 2026
Committee referred to:	Standing Committee on Health
Type of Bill:	Ordinary Bill

1. PURPOSE OF THE BILL

The principal object of the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025) is to give effect to Article 43(1)(a) of the Constitution by establishing a comprehensive legal and institutional framework for the promotion, regulation and continuous improvement of the quality of healthcare in Kenya.

The Bill sets out patient rights and corresponding facility obligations, establishes the Quality Healthcare and Patient Safety Authority to register, license, accredit and inspect health facilities, creates a specialised Health Care Tribunal to resolve health-sector disputes, and prescribes offences and penalties for non-compliance with the provisions of the Act.

2. BACKGROUND OF THE BILL

What problem does the Bill seek to address?

Kenya's health sector has for a long time grappled with cases of medical negligence, inconsistent standards of care, fragmented regulation split across the Health Act and numerous professional-regulation statutes, and a growing number of unlicensed or unregulated facilities operating with limited oversight.

There is currently no single statute that consolidates standard-setting, licensing, accreditation, inspection and enforcement in relation to the quality and safety of healthcare services, nor is there a dedicated framework guaranteeing patients an enforceable set of rights and a clear avenue for redress. This has left patients vulnerable to substandard care and has undermined public trust in both public and private health facilities.

What does the law currently provide?

The right to the highest attainable standard of health, including reproductive health care, is guaranteed under Article 43(1)(a) of the Constitution of Kenya, 2010. At the statutory level, aspects of healthcare regulation are currently addressed in a fragmented manner across the Health Act (Cap. 241), the Public Health Act (Cap. 242), and a range of professional-regulation statutes such as the Medical Practitioners and Dentists Act (Cap. 253), the Nurses and Midwives Act (Cap. 257), the Pharmacy and Poisons Act (Cap. 244), the Clinical Officers (Training, Registration and Licensing) Act (Cap. 260), each of which regulates a specific cadre of health professionals or facility type. There is no harmony in the quality and patient-safety framework. Complaints-handling, standard-setting and facility-level enforcement are similarly spread among various regulatory bodies, resulting in overlapping mandates and regulatory gaps.

Why the Bill?

The Bill is anchored on Article 43(1)(a) of the Constitution and seeks to consolidate the currently fragmented regulatory landscape into a single, coherent framework anchored on patient rights, evidence-based standards, and predictable enforcement, while also aligning Kenya's health quality assurance systems with international best practice and complementing the Social Health Insurance Act, 2023 and the Digital Health Act, 2023.

3. OVERVIEW OF THE BILL

What does the Bill regulate?

The Bill provides for the recognition and enforcement of patient rights and corresponding duties; the establishment, powers, functions and governance of the Quality Healthcare and Patient Safety Authority; the registration, licensing and accreditation of health facilities; inspections, investigations and enforcement; the establishment of a Health Care Tribunal; financial provisions for the Authority; offences and penalties; and consequential amendments to related statutes.

Responsibilities of the Cabinet Secretary

Clause 5 mandates the Cabinet Secretary responsible for health to develop national quality healthcare policies, standards, guidelines and protocols; ensure continuous improvement in healthcare outcomes; reduce inequalities in access to healthcare benefits; and take necessary steps to protect the public from disease, including ordering the closure of a health facility where required in the public interest.

Responsibilities of County Governments

Clause 6 requires each county government to –

(a) implement national policies, guidelines, protocols and standards on quality healthcare;

(b) promote equitable access to quality healthcare across the county;

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

(d) collaborate with the Authority in achieving the objects of the Act;

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

(f) maintain a county-level quality improvement programme;

(g) establish digital reporting systems integrated with the Comprehensive Integrated Health Information System established under the Digital Health Act, 2023;

(h) collect and keep quarterly quality indicators, including patient safety incidents, waiting times, clinical outcomes and patient satisfaction; and

(i) conduct public awareness campaigns on patient rights and quality healthcare standards.

Patient Rights and Corresponding Duties

Clauses 7 to 16 sets out a package of patient rights, namely the right to safe and accessible health facilities; care from a qualified and licensed healthcare professional; information and participation in healthcare decision-making; safe and quality care; timely and effective care; safe clinical processes and practices; safe and quality health products and technologies; dignity and equity, particularly for vulnerable and marginalised groups; and the right to be heard, including through a protected complaints mechanism.

Clauses 17 to 24 impose corresponding duties on health facilities, requiring them to develop and display a Patient Rights Charter; implement patient safety and quality assurance measures, including mandatory incident reporting; apply evidence-based clinical guidelines; maintain risk-management systems, including infection prevention and annual safety audits; run quality improvement programmes linked to accreditation and to access to the Social Health Insurance Fund; verify staff qualifications and provide training; and maintain professional indemnity cover.

Clause 25 sets out corresponding duties on patients, including adherence to medical advice, provision of accurate information, and executing a discharge or release of liability where treatment is declined.

The Quality Healthcare and Patient Safety Authority

Clause 26 establishes the Quality Healthcare and Patient Safety Authority as a body corporate with perpetual succession, headquartered in Nairobi but required to ensure nationwide access to its services. Clause 27 sets out its functions, which include regulating health facility infrastructure and services; registering, licensing and accrediting health facilities; enforcing quality healthcare standards; conducting inspections and investigations; accrediting facilities for empanelment under the Social Health Insurance Act, 2023; maintaining a national register of health facilities; publishing quality ratings; and advising the Cabinet Secretary and county governments on matters of quality healthcare.

Clause 29 provides for a Board of the Authority comprising a chairperson appointed by the President; the Principal Secretaries responsible for health and the National Treasury, or their representatives; the Attorney-General or a representative; the Director-General for health; a nominee of the Council of County Governors; consumer rights bodies and statutory regulatory bodies in the health sector; and the Chief Executive Officer as an ex officio member. Clauses 30 and 31 set qualification requirements for the chairperson and members, including relevant academic qualifications and at least ten years' experience, and compliance with Chapter Six of the Constitution on leadership and integrity. Clauses 35 to 37 provide for a competitively recruited Chief Executive Officer, who also serves as the Registrar and accounting officer of the Authority, and a corporation secretary.

Registration, Licensing and Accreditation of Health Facilities

Clauses 42 to 71 establish a three-stage compliance framework for health facilities. First, a health facility must obtain a certificate of registration, which may be suspended or revoked on prescribed grounds, subject to a right of appeal to the Tribunal. Second, a registered facility must obtain an annual operating licence; operating without a licence, or under a revoked licence, is an offence. Licences are categorised by facility type, including a three-tier classification for ambulances. Third, a facility may seek accreditation for quality of healthcare, valid for two years and renewable, assessed against compliance, infrastructure, human resource and clinical-guideline criteria.

The Authority is further required to operate a quality scoring and rating framework, publish results in the Gazette, and maintain a national register of health facilities.

Inspections, Investigations and Enforcement

Clauses 72 to 82 provide for the appointment of health facility inspectors by the Authority by notice in the Gazette. The inspectors are empowered to enter, search, sample, interview and inspect records at health facilities in accordance with a prescribed code of conduct. The Authority is required to maintain an inspection programme combining both announced and unannounced visits. Where there is an immediate risk of harm, an inspector may recommend temporary suspension of a service or facility. Obstruction of an inspector is an offence, and health facilities are required to keep records of the services they offer and of any recommendations arising from inspections.

The Health Care Tribunal

Clauses 83 to 86 establish the Health Care Tribunal as the successor to the HIV and AIDS Tribunal established under the HIV and AIDS Prevention and Control Act and the Dispute Resolution Tribunal established under the Social Health Insurance Act, 2023. The Tribunal is to be chaired by a person qualified to be appointed a Judge of the High Court, together with advocates and senior healthcare professionals appointed by the Judicial Service Commission for a term of three years which may be renewed once. It has original jurisdiction over disputes between health facilities and patients, and appellate jurisdiction over decisions of the Authority and other health-sector regulators. The Tribunal will not have jurisdiction in relation to criminal matters. Appeals against the Tribunal's decisions lie to the High Court.

Financial Provisions and Regulations

Clauses 87 to 92 provide for the funding of the Authority through parliamentary appropriations, accrued income, gifts, grants and donations; investment of surplus funds and annual accounts and audit in accordance with the Public Finance Management Act and the Public Audit Act. Clause 93 empowers the Cabinet Secretary, in consultation with the Authority, to make Regulations on matters including standards for emergency treatment, telemedicine and medical aesthetic procedures; accreditation and inspection procedures; facility categorisation; quality rating; and administrative fines.

Offences and Penalties

The Bill creates a graduated penalty regime for non-compliance. A health facility that fails to comply with patient safety and quality assurance measures is liable to a fine not exceeding ten million shillings. Operating a health facility without a licence attracts a fine not exceeding ten million shillings or imprisonment for a term not exceeding five years, or both, while operating under a revoked licence attracts a fine not exceeding twenty million shillings or imprisonment for a term not exceeding ten years, or both.

Obstructing an inspector, supplying false information in an accreditation application, or failing to comply with a request for records each attract fines of up to two million shillings or imprisonment of up to two years, or both. A general penalty of a fine not exceeding ten million shillings or imprisonment for a term not exceeding ten years, or both, applies to any offence for which no other penalty is prescribed.

Transitional Provisions and Consequential Amendments

Clause 99 deems existing registered health facilities to be registered under the Act, subject to re-registration within one year of commencement, and transfers staff of the Kenya Medical Practitioners and Dentists Council and other relevant regulatory bodies to the Authority on the same terms. Clause 100 and the Second Schedule make consequential amendments to fourteen existing statutes, principally the Health Act, the Public Health Act, the Pharmacy and Poisons Act, the Mental Health Act, the Medical Practitioners and Dentists Act, the Nurses and Midwives Act, the Health Records and Information Managers Act, and laws governing the training, registration and licensing of medical laboratory technicians and technologists, nutritionists and dieticians, counsellors and psychologists, physiotherapists, clinical officers, radiographers, public health officers and occupational therapists. These amendments chiefly remove or reassign health-facility regulatory functions that would otherwise duplicate the new Authority's mandate.

4. CONSEQUENCES OF THE BILL

The Bill, once enacted, will establish a comprehensive legal and institutional framework for quality healthcare and patient safety in Kenya. It will ensure that –

(a) patients have an enforceable set of rights, including access to safe, quality, timely and dignified care, and a protected mechanism for raising concerns;

(b) health facilities are subject to a coherent registration, licensing and accreditation regime, replacing the currently fragmented framework;

(c) a dedicated Authority is established with clear powers to set standards, inspect facilities and enforce compliance, complemented by a specialised Health Care Tribunal for the resolution of health-sector disputes;

(d) county governments have a defined role in monitoring, reporting on and promoting quality healthcare within their jurisdictions, in collaboration with the Authority;

(e) non-compliant conduct, including operating without a licence or under a revoked licence, is clearly penalised; and

(f) existing statutes that currently regulate aspects of health-facility quality are aligned with the new framework, reducing regulatory overlap and duplication.

The Bill will accordingly advance the constitutional right to the highest attainable standard of health under Article 43(1)(a), strengthen public confidence in the health system, and align Kenya's quality and patient-safety framework with international best practice.

5. WAY FORWARD

What next?

Pursuant to standing order 145 of the Senate Standing Orders, the Senate Standing Committee on Health shall facilitate public participation and shall take into account the views and recommendations of the public when the committee submits it report to the Senate.

What is expected of members of the public?

Members of the public, the National and county government, healthcare professional bodies, health facilities and other interested stakeholders are expected to present their views to the Senate Standing Committee on Health for consideration.

Note: This Digest reflects the Bill as passed by the National Assembly on 2nd June, 2026, and it does not have any official legal status.

Annex 4:

MATRIX ON STAKEHOLDER SUBMISSIONS TO THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILLS, NO.41 OF 2025)

REPUBLIC OF KENYA

THE SENATE — STANDING COMMITTEE ON HEALTH

STAKEHOLDER SUBMISSIONS MATRIX

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

(National Assembly Bills No. 41 of 2025

SUBMISSIONS RECEIVED

SUBMISSIONS BY INSTITUTIONS

1. The Ministry of Health (MOH)
2. Council of Governors (COG);
3. Kenya Medical Association;
4. Pharmaceutical Society of Kenya;
5. Regulatory Affairs Professionals Society of Kenya;
6. Kenya Union of Clinical Officers;
7. Health Unions Caucus (KUCO/KCOA);
8. Kenya National Union of Medical Laboratory Officers;
9. Kenya National Union of Pharmaceutical Technologists;
10. Kenya Environmental Health and Public Health Practitioners Union;
11. Kenya Union of Nutritionists and Dieticians;
12. Lab Medicine Society of Kenya;
13. Confraternity of Patients Kenya (COFPAK);
14. KELIN;
15. Rural & Urban Private Hospitals Association of Kenya (RUPHA);
16. The Paramedic Association of Kenya (TPAK);

17. IDinsight Dignity Initiative;
18. Bachelor of Clinical Medicine Graduates Association;
19. PharmAccess;
20. Pharmacare MTM Solutions;
21. Rewam Consultancy; Lishe Afrique;
22. Youth Champions for SDGs; and
23. the Kenya Union of Medical Laboratory Union & Association of Medical Laboratory Officers (submitted with over 100 co-signatories).

SUBMISSIONS BY INDIVIDUALS

1. Dr Ghalib Moseti Abdillahi;
2. Dr Joash Auka;
3. Dr Maria Ogaya Gerald;
4. Dr Royronald Ochieng Ongong'a;
5. Dr Lucy Mecca;
6. Dr Geoffrey K. Maiyoh;
7. Fatma Kasyoka Said;
8. Kennedy Kinyua;
9. George Okoth Osimbo;
10. Kinyua Murithi;
11. Collins Omollo; Tom Kauki;
12. Francis Tauwo;
13. David Wekesa;
14. Daniel Kitunga;
15. Davis Munyoki;
16. Khayiya Metcalfe;

17. Awuor Linet Owino;
18. Lilian Kerubo Nyarieko;
19. Fridah Mukiri John;
20. Ndege James Muchira;
21. Hadija Bisharo;
22. Isaac Kiplimo Sambu;
23. James Kago;
24. Beatrice Mwanzia;
25. Lydia Nyawira Mburia;
26. Felix Ouko;
27. Isiah Matundura;
28. Fredrick Osewe;
29. Victor Osoo;
30. Chacha Omahe;
31. Scovia Adema;
32. Judy Mso;
33. Ken Ochoggia;
34. Maramba Morena;
35. Emmanuel Chiboya;
36. Levis O. Wandolo;
37. Walter Lesaatin;
38. Sheero M. and
39. Aidah Mercy and co-signatories.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
1	**General**	**Kenya Union of Clinical Officers (KUCO) / Kenya Clinical Officers Association (Health Unions Caucus)**	Withdraw the Quality Healthcare and Patient Safety Bill, 2025 in its entirety and instead amend the Health Act, 2017. In the alternative, adopt the amendments set out in the memorandum.	Over 80% of the content of the Bill is already provided for in existing legislation and policy (Health Act 2017, Public Health Act, Clinical Officers Act, MPDA, Nurses Act, MLTT Act, Pharmacy and Poisons Act, KQMH policy, National Policy on Patient Safety). The judgment of Justice Weldon Korir (September 2022) directed amendment of the Health Act, which is a shorter and more cost-effective route. Creating a new SAGA also contravenes the Cabinet Resolution of 2025 directing merger, dissolution or declassification of State agencies in view of the tight fiscal space.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya.
2		**Kenya National Union of Medical Laboratory Officers (KNUMLO)**	Withdraw the Bill and amend the Health Act, 2017 instead; alternatively adopt the proposed amendments.	The Bill creates duplication and confusion. The Ministry of Health developed the Bill without involving implementers of the policy or legislation. The real threats to quality are financing, HR shortages, strikes, weak digital infrastructure and political interference and not the absence of law.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law. kg
3		**Kenya Union of**	Withdraw the Bill and instead	The Bill duplicates existing	**Reject:** The Bill will improve the

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
		Nutritionists and Dieticians (KUNAD)	amend the Health Act, 2017.	statutes and will not change the quality of healthcare; The Kenya Health Professions Oversight Authority (KHPOA) should instead be empowered.	quality of care and patient safety in Kenya. The Bill does not duplicate any other law. The role of KHPOA is to regulate professionals while the role of the Quality Healthcare and Patient Safety Authority is to register, license and accredit health facilities.
4		**Bachelor of Clinical Medicine Graduates Association (BCMGA)**	Withdraw the Bill and amend the Health Act, 2017; alternatively adopt the amendments proposed.	The Bill duplicates roles already assigned under other Acts and retains the weak quality assurance model in which a single entity registers, licenses and accredits facilities. KENAS already accredits conformity assessment bodies.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.
5		**Kenya Union of Medical Laboratory Union & Association of Medical Laboratory Officers (Aidah Mercy and 100 other co-signatories); Walter Lesaatin; Sheero M.**	Withdraw the Bill and amend the Health Act, 2017; alternatively adopt the clause-by-clause amendments proposed.	The Bill was developed without involving implementers; it duplicates existing law and concentrates registration, licensing and accreditation in one entity.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.
6		**Chacha Omahe**	Withdraw the Bill and amend the Health Act, 2017 in line with the September 2022 High Court	Creating a parallel authority duplicates roles and contradicts the Cabinet Resolution of 21st	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
			judgment.	January 2025 and risks regulatory confusion.	any other law.
7		**Levis O. Wandolo**	Withdraw the Bill and amend the Health Act, 2017. Align budgetary allocation to health with the Abuja Declaration (15%); develop a framework for annual employment of 12,000 health workers; designate KHPOA as the Quality of Healthcare Authority; fully operationalise KHPOA and the Kenya Health Human Resources Advisory Council; conclude and implement CBAs and Recognition Agreements.	The real issues threatening quality are financing, staff shortages, strikes, poor digital infrastructure, demotivation, weak national–county coordination, political interference and over-legislation without implementation.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.
8		**Judy Mso; Ken Ochoggia; Maramba Morena; Emmanuel Chiboya**	Withdraw the Bill and amend the Health Act, 2017, or adopt the amendment to clause 18 propose.	The Bill creates duplication and confusion and will not enhance the quality of healthcare.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.
9		**Isiah Matundura**	Withdraw the Bill; scope of practice should be implemented by regulatory bodies.	The Bill is of lesser value than the Health Act, 2017. The Director-General is partial, favours one cadre out of more than 22 cadres, and has a conflict of interest.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.
10		**Felix Ouko**	Strengthen the existing regulatory bodies rather than transferring their functions.	The Bill usurps the functions of the various regulatory bodies in determining scope of practice and vests them in an individual (the Director-General) who is not	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
				subject to oversight and is prone to administrative overreach.	
11		**Awuor Linet Owino (Medical Laboratory Technologist)**	Reject the Bill in its current form unless amended.	The Bill introduces dangerous regulatory overlaps, strips specialised professionals of their mandates and punishes frontline health workers for systemic State underfunding.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.
12		**Victor Osoo (Pharmaceutical Technologist / Mental Health Practitioner)**	Strengthen the existing laws and institutions instead of enacting a new law that overburdens the industry.	The health sector is already over-regulated, with 18 regulators imposing different levies and charges. Multiple regulation raises compliance costs, breeds corruption and duplicates roles. Quality is already within the mandate of every existing regulator.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The existing agencies regulate health professionals while the basis of the Authority under this Bill is to regulate health facilities.
13		**Khayiya Metcalfe (Medical Laboratory Professional)**	Before the Bill proceeds, the Committee should clarify: the necessity of a new Authority; how its functions differ from KMLTTB and other councils; whether it will license/inspect facilities already licensed elsewhere; whether it will regulate individual professionals; the estimated cost and whether a cost-benefit analysis was done; why existing institutions cannot be strengthened instead; how laboratory quality assurance, EQA and proficiency testing will be	Kenya already has professional councils and regulatory authorities. Duplication of inspections, fees and compliance requirements must be prevented and clear lines of responsibility established to avoid conflicting investigations.	**Reject:** The Bill will improve the quality of care and patient safety in Kenya. The Bill does not duplicate any other law.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
			safeguarded; how responsibility will be shared where a patient-safety incident involves laboratory testing; and who is responsible for point-of-care testing (POCT) oversight.		
14		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Support the Bill and the consolidation of facility registration, licensing and accreditation into a single Authority, provided the consolidation replaces existing requirements rather than adding to them, and provided the safeguards on the exercise of power are as self-executing as the powers themselves.	Every power conferred by the Bill takes effect on commencement, but many protections do not operate until the Cabinet Secretary or Authority takes a further step (a regulation, a code of conduct, a Gazette notice, an appointment).	**Accept:** The Bill will improve the quality of care and patient safety in Kenya
15		**Council of Governors (CoG)**	Retain the Bill but amend it to embed clinical governance, organisational learning, patient partnership and county-level implementation. The key additions sought include county quality governance; clinical governance; just culture; learning from adverse events; continuum of care anchored in the Primary Health Care Act, 2023; recognition of existing accreditation; and patient partnership.	The Bill should go beyond setting regulatory standards to build a sustainable culture of safety. The proposals are consistent with the WHO Global Patient Safety Action Plan 2021–2030 and advance Universal Health Coverage while respecting Articles 1(4), 6(2) and 189 of the Constitution.	**Partly accept:** the committee resolves that an amendment to clause (4) of the Bill be done to provide for promotion of continuous and integrated quality healthcare across all levels of care, including community health services, primary healthcare, referral services, rehabilitative care and palliative care.
16		**Fatma Kasyoka Said (Researcher, University of Nairobi)**	Retain and strengthen the Bill by: (i) embedding Continuous Quality Improvement (CQI) as the overarching	Legislation alone does not guarantee improved health outcomes. Comparative experience from Singapore,	**Accept.**

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
			philosophy; (ii) expressly recognising patient-centred care, Primary Healthcare, Community Health Promoters, digital health governance, workforce development, research, innovation, performance measurement and evidence-based decision-making; (iii)clarifying the Authority's relationship with existing regulators; (iv)clarifying the national/county division of functions; (v) providing sustainable financing and financial accountability; and (vi)introducing a statutory requirement for periodic review of the Act.	Australia, South Africa and Brazil shows that effective systems combine regulatory oversight with continuous quality improvement, transparent performance monitoring, patient-centred care, digital health governance and cooperative intergovernmental arrangements.	
17		**Kennedy Kinyua (Healthcare professional and medical educator)**	Support the Bill subject to amendments. Retain the core patient-safety architecture but establish a clear 'facility regulator and professional regulator' boundary, protect devolved county functions and introduce a just-culture incident reporting regime.	The Bill's success depends on whether it creates a learning health system or another layer of fragmented regulation. Sequential approvals, fees and inspections alongside county, Digital Health Agency and SHA processes create delay, cost and	**Accept:** The Bill clearly separates the regulation of healthcare professionals (done by existing regulatory agencies) and the regulation of health facilities which will be the responsibility of the Quality Healthcare and Patient Safety Authority.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
				inconsistent decisions.	
18		**Dr Joash Auka (Consultant Radiologist, KMTC)**	Amend the Bill to resolve nine identified conflicts with existing law before it proceeds.	The Bill's provisions conflict with, duplicate or leave gaps against the devolution framework, the Health Act (Cap. 241), the Digital Health Act, 2023, the Social Health Insurance Act, 2023, the Medical Practitioners and Dentists Act (Cap. 253), the Public Health Act (Cap. 242), the Nuclear Regulatory Act and Radiographers Act and the Fair Administrative Action Act.	**Accept:** The Bill clearly separates the regulation of healthcare professionals (done by existing regulatory agencies) and the regulation of health facilities which will be the responsibility of the Quality Healthcare and Patient Safety Authority.
19		**Dr Ghalib Moseti Abdillahi (Consultant Obstetrician & Gynaecologist)**	Support the Bill subject to the following amendments (1) vest scope of practice in the statutory regulators (s.18(1)(c)); (2) confine the Tribunal to decisions of the Authority (s.84(4)); (3) reserve named regulator and provider seats on the Board and define the chairperson's qualification (ss.29, 30); (4) require clinical inspections by registered professionals (ss.72–76); (5) preserve concurrent/joint clinical inspection powers for the councils and insert full transitional provisions (Second Schedule and s.99).	The Bill draws a sensible line such that the Authority regulates facilities; the councils regulate professionals but does not hold that line consistently. The effect, if unamended, is not a clean transfer of facility regulation but a partial absorption of professional regulation achieved through general provisions and a schedule of consequential amendments.	**Partly Accept:** The Committee agrees that there is need to confine the role of the healthcare Tribunal to the decisions of the Authority. On reserving positions for named regulators to the Board of the Authority, the Bill already addresses the same by preserving four seats for health professionals. The scope of practice is vested in the Director General for health who is a technical officer on health matters.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
20		**Millicent Olulo (PharmAccess)**	Separate accreditation and certification from registration and licensing.	As drafted, the Bill concentrates regulatory, certification and accreditation functions in one body, deviating from international standards and creating a conflict of interest between regulatory oversight and certification. KENAS already oversees Conformity Assessment Bodies in Kenya, and SafeCare (KENAS-accredited) has assessed close to 2,000 facilities. Mutual recognition reduces regulatory burden, positions Kenya in the international market and enables cross-border reimbursement by insurers.	**Reject:** the mandate of KENAS is limited to assessing and accrediting conformity assessment bodies in Kenya and should not be misconstrued as extending to the setting and enforcement of health standards. The responsibility for setting health standards rests with the Cabinet Secretary for health and their enforcement must be carried out through a body established within the health sector.
21		**Pharmacare MTM Solutions (Dennis Bogonko Omboga)**	Support the Bill, but expressly recognise Medication Therapy Management (MTM), medication reconciliation and structured medicines-use review as components of 'quality healthcare'; recognise Pharmaceutical Technologists' scope in patient-safety functions; integrate pharmacovigilance and medication-error reporting into inspection and licensing standards; extend quality standards to community pharmacies and primary care; require CPD as a condition of quality assurance; and harmonise standards with SHA	Medication-related harm is among the most common, most preventable and most under-reported causes of patient harm in Kenyan health facilities. A Bill on quality healthcare that does not explicitly name and structure medicines-use safety leaves one of the largest sources of preventable harm outside its architecture.	**Partly Accept:** The Bill will improve the quality of care and patient safety. The issue of regulation of pharmaceutical technologists and pharmacies is not the primary concern of this Bill and can be addressed through this Bill.

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No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
			facility-empanelment requirements.		
22		**Rewam Consultancy**	Provide for a phased rollout of accreditation and inspection with clear timelines, pilot programmes and a grace period of 12–18 months before penalties apply; clarify Tribunal jurisdiction and establish referral protocols; adopt a risk-based inspection model using digital self-assessment and remote monitoring; allocate part of the Authority's budget to training and technical assistance for facilities in underserved counties; and require publication of annual reports on inspection outcomes, licensing decisions and Tribunal rulings in accessible formats including online dashboards, with a public rating or certification system.	Without clear operational guidelines there is a risk of delays, inconsistency or regulatory capture. Private and public facilities operate under different resource constraints and a one-size-fits-all compliance approach disadvantages smaller and rural facilities.	**Partly accept:** the committee resolves to limit the jurisdiction of the tribunal to decisions of the Authority under this Bill.
23		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Transition the Bill from a punitive framework focused on fines, closures and criminalisation to a supportive system addressing resource deficits and the structural causes of medical errors; replace centralised control with a collaborative regulatory network respecting the mandates of existing boards and county governments; provide full institutional indemnity	The Bill's philosophical orientation is heavily punitive, its architecture centralised, its workforce protection minimal and its governance narrow excluding the largest professional classes, including pharmaceutical technologists.	**Reject:** Besides addressing resource shortage issues, fines are necessary to enforce compliance.

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			for employees acting within their scope of employment; and broaden governance to reflect the multi-disciplinary nature of clinical teams.		
24		**Beatrice Mwanzia (Orthopaedic and Trauma Technician)**	Support the Bill and additionally: establish minimum safe staffing standards; strengthen emergency and trauma care standards; mandate continuous professional development; protect healthcare workers who report unsafe practices; promote multidisciplinary quality improvement; and strengthen patient education and public awareness.	The Bill is a significant step towards strengthening Kenya's health system and protecting patients, but requires these additions to be effective.	
25		**Isaac Kiplimo Sambu (Medical Laboratory Technologist, Uasin Gishu County)**	Strengthen human resources for health through automatic promotion, redesignation, harmonised career progression, CPD and occupational safety; establish an independent Health Service Commission; create Health Products and Technologies Units (HPTUs) at national and county level; provide ring-fenced funding for laboratory commodities, blood transfusion, emergency outbreak reserves, quality assurance and digital health; strengthen patient safety through IPC committees, clinical audits, haemovigilance, pharmacovigilance and incident reporting; support interoperable	These measures will strengthen healthcare quality, protect patients and health workers, improve laboratory and public health emergency response systems, and enhance accountability in the health sector.	**Partly accept:** On the issue of reporting on quality of care and patient safety, the Bill already requires the CS for health to table a report to parliament. The matters of human resource can however be addressed through a policy rather than a law. The committee rejects the proposal for establishment of an independent health commission as it cannot be achieved through this Bill.

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			laboratory information systems; mandate annual reporting on patient safety, laboratory performance, workforce and biosafety incidents; require comprehensive biosafety and biosecurity programmes in all laboratories; and insert a clause establishing a risk-based Biosafety, Biosecurity and Sample Management Allowance for medical laboratory personnel.		
26		**Francis Tauwo**	Support the Bill with amendments amendments, including: clearly distinguishing facility regulation from professional regulation; strengthening patient representation on the Board; protecting healthcare workers; whistleblower protection; clarifying county funding responsibilities and providing conditional grants; defining measurable national quality indicators (maternal mortality, surgical site infection rates, medication errors, hospital-acquired infections, patient satisfaction, waiting times, equipment downtime, commodity stock-outs); mandatory clinical governance committees; and improved complaints procedures.	These amendments would make the Bill more balanced, reduce regulatory overlap, strengthen accountability, protect both patients and health workers, and promote continuous quality improvement rather than relying primarily on enforcement. The Bill should also address stand-alone establishments such as laboratories, chemists and alternative medicine providers.	**Partly accept:** The Bill clearly separates regulation of health facilities from the regulation of health professionals. It also promotes continuous quality improvement. Further, the Bill protects both patients and healthcare workers who are both important ins ensuring that quality of care and patient safety is attained.
27		**Youth Champions for SDGs**	Reserve at least three seats on the governing Board of the Authority	Young people aged 15–35 constitute a significant portion of	**Reject:** Board composition is governed by Mwongozo guidelines.

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			for youth representatives nominated through a transparent, competitive process; establish a Youth Advisory Panel to the Authority; require accredited facilities to meet minimum youth-friendly service criteria (confidential, non-discriminatory care for adolescents; sexual and reproductive health services without parental-consent barriers in line with existing law; staff trained in youth communication and mental health first aid); expressly include mental health and psychosocial support as core components of patient safety; mandate routine mental health screening in primary care and emergency settings with clear referral pathways; and leverage digital platforms for youth reporting and participation.	Kenya's population but face unique barriers including cost, stigma, absence of youth-friendly services and limited mental health support. The Bill's current draft does not address youth-specific needs or ensure youth representation in the governance of the Authority.	The inclusion of three seats for the youth would enlarge the composition of the Board bend the recommended nine (9) members.
28		**Lishe Afrique**	Amend the definition of 'quality healthcare' to include evidence-based nutrition assessment, counselling and therapeutic feeding as standard components of patient care; require licensed facilities to have access to qualified nutrition professionals; require the Authority to develop and enforce minimum nutrition service standards by facility level and include nutrition	Malnutrition and diet-related non-communicable diseases remain major drivers of poor health outcomes, yet nutrition services are under-regulated and under-resourced. The Bill does not recognise nutrition assessment and dietary care as essential elements of quality healthcare, and gives the Authority no clear mandate over	**Reject:** The definition of quality healthcare as provided for in the Bill is sufficient to address the concerns raised.

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			indicators in inspection checklists; strengthen patient rights to include the right to clear, culturally appropriate nutrition information and dietary plans (including written or digital dietary guidance at discharge for diet-sensitive conditions); and mandate routine collection and reporting of nutrition-related data.	nutrition standards.	
29		**The Paramedic Association of Kenya (TPAK)**	Expressly recognise licensed emergency medical services as part of Kenya's healthcare delivery system and confirm that quality and patient-safety standards apply equally to prehospital care; require licensed ambulance providers to maintain a clinical governance framework (medical oversight, clinical practice guidelines, clinical audit, incident reporting, morbidity and mortality reviews, documentation standards, risk management); empower the Cabinet Secretary to develop national prehospital clinical standards; and mandatory life-support recertification; and provide for reporting and investigation of prehospital patient-safety incidents.	A patient's journey through the health system very often begins at the roadside or the scene of an emergency, and the care delivered in those first minutes frequently determines whether the patient survives to reach a facility at all. Yet the emergency clinical workforce has no clear legal definition, protected title or settled regulatory framework in Kenya. Universal Health Coverage cannot be achieved unless it begins at the first point of contact.	**Partly Accept:** The definition of emergency medical treatment covers pre-hospital care.
30		**IDinsight Dignity Initiative**	Support the Bill and strengthen it by defining and continuously	The Bill enforces its licensing and financing provisions with	**Accept:** Several measures provided in the Bill can be used on enforcing

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			measuring patient satisfaction, and by backing patient rights with enforceable practice rather than posters (see clause-specific rows below).	fees, inspections, penalties of up to fifty million shillings and the link to SHIF empanelment, but the patient rights in Part II have no such backing. Progressive realization, content deferred to Regulations, and no consequence for violation. In a survey of 1,200 respondents across 14 counties, three-quarters rated dignity as very or extremely important, 85% would wait an hour longer and 89% would travel a mile further for more respectful treatment, yet 68% had suffered at least one serious violation of their dignity.	patients' rights including closure of health facilities and fines.
31		**Pharmaceutical Society of Kenya (PSK)**	Support the Bill subject to amendments protecting the medicines-regulatory chain, recognising pharmaceutical care and medication safety, and preserving the mandate of the Pharmacy and Poisons Board.	The Bill must address the entire medication-use pathway and recognise the patient-facing role of pharmacists, while avoiding a competing meaning for pharmacy premises already defined under the Pharmacy and Poisons Act (Cap. 244).	**Accept:** The Bill preserves the mandate of the Pharmacy and Poisons Board and only provides for health facility regulation.
32		**Regulatory Affairs Professionals Society of Kenya (RAPSK)**	Take into account that the Bill introduces the risk of overlapping or conflicting regulatory mandates and may undermine the Pharmacy and Poisons Board's effectiveness as the statutory regulator of health products and technologies.	Multiple regulators have long been a major challenge in the health sector, evident in ongoing jurisdictional overlaps between PPB, KMLTTB, KMPDC, KEBS and the Anti-Counterfeit Authority. An additional layer of	**Accept:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.

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				regulation could lead to regulatory confusion, increased operational costs ultimately borne by patients, and could undermine the very patient-safety outcomes the Bill seeks to improve.	
33		**Lab Medicine Society of Kenya (LMSK)**	Adopt a collaborative regulatory framework that preserves KMLTTB's statutory mandate over the professional and technical practice regulation of medical laboratory services while allowing the Authority to regulate health facilities.	Clause-by-clause comparison of the Second Schedule against Cap. 253A shows that the Bill repeals or dismantles, in explicit and identifiable terms, the statutory mechanisms by which KMLTTB regulates laboratory professional practice while every other major health professional regulator examined retains a substantially intact statutory framework after the same Second Schedule takes effect.	**Accept:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.
34		**Lilian Kerubo Nyarieko; Fridah Mukiri John; Ndege James Muchira (Medical Laboratory Technologists)**	Preserve KMLTTB's specialised statutory mandate over medical laboratories; retain laboratory-specific registration and inspection; protect professional laboratory supervision; preserve laboratory-specific professional standards; establish a coordinated regulatory model between the Authority and KMLTTB; protect the professional leadership pathway for laboratory professionals; reconsider the	The central question is not how many regulators should Kenya have but 'who is technically accountable when a laboratory fails. A hospital may satisfy general facility requirements while its laboratory remains deficient in quality control, specimen integrity, staffing, equipment validation, microbiological practice or technical supervision. This is not	**Accept:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.

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			consequential amendments to Cap. 253A (repeal of s.21, amendment of s.25 and deletion of s.40(g)); and require meaningful stakeholder consultation before laboratory regulatory functions are transferred.	duplication; it is layered regulation based on different areas of expertise. A licence to operate a health facility should not automatically become a licence to provide every specialised healthcare service within that facility.	
35		**Daniel Kitunga (Medical Laboratory Officer)**	Amend the Bill to: provide that laboratory inspections be undertaken jointly with or in consultation with KMLTTB; require the Authority to recognise licences issued by professional regulatory bodies; require laboratory quality standards to be developed in consultation with KMLTTB; include an express provision that nothing in the Act limits the statutory mandate of professional regulatory bodies; require professional-misconduct investigations to be conducted in collaboration with the relevant regulator; clarify that the Tribunal shall not exercise disciplinary jurisdiction reserved to professional regulators; provide for representation of regulators on advisory and technical committees; and insert a harmonisation clause.	The Bill introduces an Authority with powers that substantially overlap KMLTTB's statutory functions. Dual inspections would result in duplication, conflicting findings, increased administrative burden and unnecessary compliance costs, without necessarily improving patient safety.	**Accept:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.
36		**Davis Munyoki**	Amend the Bill to clearly preserve	Duplicate licensing and	**Accept:** The Bill already separates

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		(Medical Laboratory Technologist, RKA Specialist Hospital)	the statutory mandate of KMLTTB and other councils; define the Authority as a coordinating and quality assurance body rather than duplicating licensing and inspection functions already assigned to specialised regulators; establish mechanisms for collaboration and information sharing; and include provisions expressly preventing multiple regulators from carrying out overlapping licensing and inspection over the same facility unless jointly coordinated.	inspection by two statutory bodies performing similar functions increases administrative costs, creates uncertainty over regulatory responsibility and reduces operational efficiency without improving patient safety.	the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.
37		**David Wekesa**	Adopt the principle that the Authority should regulate quality of healthcare and patient safety at health-system and facility level, but should not assume, duplicate, transfer or override KMLTTB's statutory professional-regulatory mandate. Delete the provisions listed in the memorandum and insert an express statutory saving clause protecting KMLTTB's mandate under Cap. 253A.	Section 60 of the Health Act expressly provides that regulatory bodies retain responsibility for inspection, monitoring and evaluation of the services and professionals they regulate, and provides for coordination through KHPOA. The desired outcome is not regulatory fragmentation but a clear division of responsibility.	**Accept:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.
38		**James Kago (Medical Laboratory Science graduate)**	Amend the Bill so that the Authority and KMLTTB work collaboratively, preserving each institution's specialised mandate while avoiding unnecessary duplication; preserve the laboratory superintendent	Medical laboratory services are highly technical and directly influence clinical diagnosis, treatment decisions, disease surveillance and public health. The superintendent role promotes	**Accept:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.

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			licensing framework.	professional accountability, quality management and career progression within medical laboratories.	
39		**Dr Royronald Ochieng Ongong'a (Medical Laboratory Scientist / Chemical Pathologist)**	Amend to require the Authority to enter into Memoranda of Understanding with sectoral boards including KMLTTB; and confine the Authority's direct enforcement powers to facility-level and systemic quality indicators, leaving individual licensure, discipline and scope-of-practice matters to the relevant board.	Over-centralisation of regulatory power in a single Authority risk subordinating technical, profession-specific regulatory judgment to a generalised bureaucratic process, undermining the very quality standards the Bill seeks to protect. Parliament has already vested regulatory competence in specialised boards; a new statute ought to complement, not silently supplant, that architecture.	**Reject:** the facility level regulation, licensing and accreditation should remain with the Authority.
40		**Dr Lucy Mecca (Pharmacist)**	Amend the Bill to expressly define the respective responsibilities of the Authority and the Pharmacy and Poisons Board in relation to the licensing, inspection and enforcement of pharmacy premises, and clarify which functions are transferred from PPB.	The Bill amends section 2 of the Health Act to include pharmacies within the definition of a health facility, amends sections 3A and 3B of the Pharmacy and Poisons Act and repeals sections 23 and 23A, but does not state which functions are transferred or how the two regulators will exercise their respective mandates. For example, it is unclear how a facility found in possession of counterfeit medicines would be handled.	**Reject:** The Bill clearly delineates the regulation of professionals and health facilities. There is therefore no clash of mandate between the Pharmacy and Poisons Board and the Authority established by the Bill.

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41		**Hadija Bisharo (Medical Laboratory Technologist)**	Amend the Bill to require that all diagnostic processing and verification be strictly overseen by KMLTTB-registered and licensed professionals; delete the clause duplicating laboratory inspection mandates and maintain KMLTTB as the single autonomous body for validation of diagnostic facility standards; and require mandatory peer-review vetting and KMLTTB examination before any foreign-trained laboratory professional is licensed.	Allowing cross-profession reporting invites misdiagnosis and medical litigation. KMLTTB has unique technical competency for validation of facility standards in Kenya. A weak laboratory system means a broken healthcare system.	**Reject:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.
42		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend the Bill to recognise provider rights and protections, strengthen Board and Tribunal representation, establish an Inspectorate Unit, and provide proportionate offences.	Provider welfare underpins patient safety. The Bill regulates the conduct of healthcare workers in detail while remaining silent on the conditions under which they are expected to work.	**Reject:** The Bill sufficiently protects the patients and health providers rights.
43		**Dr Maria Ogaya Gerald (Consultant Paediatrician, Homa Bay County)**	Clearly define the Authority as a national quality coordination and oversight body rather than an additional professional regulator; require multidisciplinary committees to include appropriate physician representation where clinical decisions are made; preserve professional accountability frameworks; harmonise accreditation processes and	Several provisions blur the distinction between system regulation and professional regulation, creating potential for regulatory overlap and duplication of statutory functions while making accountability unclear. Quality legislation should regulate systems, not redefine professional competence.	**Reject:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.

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			recognise approvals issued under existing laws; limit the Authority to institutional quality investigations; require peer review by appropriately qualified professionals within the relevant speciality during quality audits; and align accountability with decision-making authority and resource control.		
44		**Dr Geoffrey K. Maiyoh (Moi University)**	Support the Bill with four targeted amendments benchmarked against Switzerland, Norway, the Netherlands, Japan and Taiwan: a minimum proportion of unannounced inspections; a no-fault compensation pathway; public quality dashboards; and whistleblower protection.	These five countries demonstrate that world-class patient safety and affordable, accessible justice are achievable through smart, evidence-based regulation.	**Partly accept:** further guidelines on the announced and unannounced health facility inspections will be provide through regulations by the Cabinet Secretary.
45	**Long Title / Objects and Purpose (clause. 3)**	**George Okoth Osimbo**	Insert a new paragraph immediately after paragraph (e): "(f) promote coordination and collaboration with Health Professional Regulatory Bodies established under written law in the regulation of quality healthcare and patient safety."	The Bill should expressly recognise the complementary role of existing statutory regulators. This avoids duplication of functions, promotes institutional coordination and preserves Parliament's intent in establishing profession-specific regulatory bodies.	Agree.
46		**Dr Royronald Ochieng Ongong'a**	Insert an express savings/complementarity clause providing that the Authority shall	The Bill does not expressly recognise existing professional regulatory boards (KMLTTB,	**Reject:** The Bill already separates the mandate of professional bodies from the regulation of health

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			exercise its functions without derogating from, or duplicating, the statutory mandates of existing cadre-specific regulatory boards, and shall collaborate with them through Memoranda of Understanding.	NCK, PPB, KMPDC) as co-regulators, creating a risk of institutional conflict and duplicated mandates.	facilities which will be the mandate of the Authority.
47		**Fatma Kasyoka Said**	Expand the objects to expressly include Continuous Quality Improvement (CQI), patient-centred care, innovation, research and evidence-based decision-making.	The objects place limited emphasis on continuous quality improvement and innovation. A proactive and adaptive healthcare quality system focused on continuous improvement is required.	
48		**Lab Medicine Society of Kenya (LMSK)**	Insert a new clause after clause 3 providing that; "Nothing in this Act shall be construed as transferring, limiting or extinguishing the statutory powers and functions of the professional regulatory bodies established under written law."	The Bill does not state its relationship to existing professional regulatory statutes. As drafted, the Authority's mandate is open to being read as superseding Cap. 253A and comparable professional Acts.	**Reject:** The Bill already separates the mandate of professional bodies from the regulation of health facilities which will be the mandate of the Authority.
49	**Clause 2 – Interpretation**	**Kenya Medical Association (KMA)**	Insert an express definition of "patient safety"; Patient safety means "a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that	"Patient safety" anchors the Bill's stated objects under clause 3 but is nowhere defined. A central, undefined term risks inconsistent interpretation and enforcement.	**Reject:** The term should adopt its natural meaning. The definition will limit the safeguards already provided for in the Bill in ensuring quality of care.

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			consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely, and reduce its impact when it does occur."		
50		**Kenya Medical Association (KMA)**	Define "medical aesthetic procedure" by its purpose — a procedure performed primarily to alter or enhance physical appearance — leaving risk-based regulation to apply according to each procedure's actual risk profile.	The current definition builds an assumption of inherent risk into the definition itself. Many such procedures carry no more risk than routine outpatient care.	**Reject:** The definition is sufficient.
51		**KELIN**	Delete the phrase "quasi-medical" from the interpretation of medical aesthetic procedure.	"Quasi-medical" is not defined in any Kenyan law on health. Its application could cause challenges in interpreting the scope of services regulated, because most services provided by aestheticians could be placed in a quasi-medical category.	**Reject:** The definition is sufficient.
52		**Kenya Medical Association (KMA)**	Define "patient-centred care" simply as care that responds to an individual patient's needs, values and preferences, deleting the aspirational requirement to foster partnerships.	An undefined, subjective standard cannot be consistently assessed for compliance. A partnership requirement is difficult to operationalise or assess and can remain implicit in good practice without a statutory definition.	**Reject:** The definition is sufficient.
53		**Kenya Medical Association (KMA)**	Expressly extend the definition of "adverse event" to cover harm materially caused or contributed to	The definition currently covers harm caused by medical management only. Algorithmic	**Reject:** The definition is sufficient.

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			by an algorithm or automated clinical recommendation.	contribution to patient harm is untested under the Bill's own terms.	
54		**Pharmaceutical Society of Kenya (PSK)**	Insert the definitions of – "Medication safety" (the prevention, identification, reporting, investigation and reduction of avoidable harm arising at any stage of the medication-use process); "Pharmaceutical care" (the responsible provision of medicine-related care by a registered pharmacist), and "Pharmacy premise" (as assigned under the Pharmacy and Poisons Act, Cap. 244).	Clear definitions ensure the Bill addresses the entire medication-use pathway and recognises the patient-facing role of pharmacists.	**Reject:** These definitions are best addressed under the Pharmacy and Poison Act.
55		**IDinsight Dignity Initiative**	Insert a new definition in proper alphabetical sequence: "patient satisfaction" includes patients' self-reported experience of dignity and respectful care, measured using validated patient-reported instruments;	The Bill requires patient satisfaction to be monitored (clauses 6(i), 22 and 59(g)) and reported (clause 92(3)(a)) but never defines it. Primary legislation should set rights and duties, with regulations and oversight clear on methods.	**Reject:** The term should preserve as much as possible its natural meaning.
56		**George Okoth Osimbo**	Delete the words "and persons" from the definition of "accreditation for quality of healthcare".	Accreditation of persons is already governed by the statutory regulators. Retaining the words "and persons" creates an	**Reject:** The word "persons" does not automatically translate to the regulation of healthcare professionals. A person in law

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			Insert a new definition of "Health Professional Regulatory Body" Insert into the definition of "quality of healthcare" the words "developed in consultation with the relevant Health Professional Regulatory Bodies" after the words "evidence-based standards".	overlapping accreditation mandate contrary to Articles 10, 47 and 232 of the Constitution. The Bill repeatedly assigns functions intersecting with statutory regulators but does not define them.	includes an artificial person such as an incorporated entity.
57		**Kinyua Murithi**	Amend the definition of the term "emergency medical treatment" to read: "Immediate care given to a person to save life, stop intense pain, or ameliorate severe injury pending definitive treatment or management of the cause of threat to life."	The current definition is too broad and would capture preventive and promotive health services such as vaccination and ante-natal clinics.	**Reject:** The current definition is sufficient to meet the objectives of this law.
58		**Tom Kauki**	Insert the following definitions; "Falsified health product and technology" means health products and technologies that are deliberately or fraudulently misrepresented in identity, composition or source; "Substandard health product and technology" means authorised health products and technologies that fail to meet either their quality standards, specifications, or both.	Consequential to the proposed reporting duties under clause 14(2) as proposed by the stakeholder; the terms must be defined for the reporting obligation to be enforceable.	**Reject:** These terms are best addressed under the Pharmacy and Poison Act which is the law that deals with health products and technologies.

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No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
59		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Insert a new definition for the term "Systemic Institutional Failure". The definition would separate individual clinician actions from resource deficits caused by institutional failures	The Bill omits a clear definition, creating potential ambiguity in liability assessments.	**Reject**
60		**David Wekesa**	Delete the amendment to section 2 of Cap. 253A insofar as it introduces the definitions of "practising certificate"" and "tribunal" into that Act.	Introducing tribunal terminology into Cap. 253A creates a direct statutory interface between the new Tribunal and the professional disciplinary statute, risking a shift of professional accountability from KMLTTB to an external tribunal-based pathway unless the Bill expressly preserves the Board's primary professional disciplinary role.	
61	**Clause 4 – Guiding principles**	**Confraternity of Patients Kenya (COFPAK)**	Add "Patient Engagement and Empowerment" to the principles for implementation of the Act.	"Patient Engagement and Empowerment is perhaps the most powerful tool to improve patient safety" (WHO Global Patient Safety Action Plan). This fosters active participation and shared decision-making between the recipient of care and healthcare providers.	**Accept:** This will foster active participation and shared decision-making between the recipient of care and healthcare providers.
62		**KELIN**	Supplement the list of principles to mirror Article 10 of the Constitution;	Alignment with the national values and principles of governance under Article 10 of the Constitution of Kenya, 2010.	**Accept**

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
			insert a new sub-clause 4(e) — transparency.		
63		**Kenya Medical Association (KMA)**	Insert a new paragraph (e): "safe, effective, timely, efficient and integrated care, delivered by an adequately staffed and competent health workforce, as the foundation on which patient-centred care and accountability under this Act depend."	The guiding principles name equity, quality, protection of well-being, patient-centred care and accountability, but do not name safety, effectiveness, timeliness, efficiency, integration or adequate human resource capacity. This anchors the whole Act in the full set of internationally recognised quality dimensions (WHO/OECD/World Bank; IOM).	**Reject**
64		**Council of Governors (CoG)**	Insert a new guiding principle to provide: "Implementation of this Act shall promote continuity and integration of quality healthcare across all levels of care, including community health services, primary healthcare, referral services, rehabilitative care and palliative care."	Healthcare quality should be viewed as a system property rather than a facility-specific function. Anchoring this principle in the Primary Health Care Act, 2023 ensures the Bill extends quality improvement across the entire continuum of care rather than treating primary care as an afterthought.	**Accept**
65		**George Okoth Osimbo**	Insert a new paragraph after (d): "(e) collaboration and mutual recognition of statutory mandates of Health Professional Regulatory Bodies established under written law."	Mutual recognition of statutory mandates will minimise regulatory overlap, eliminate conflicting directives and enhance coordinated oversight, consistent with Articles 10 and 232 of the Constitution and	**Reject**

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				OECD principles of good regulatory practice.	
66		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	After clause 4, insert: "(x) Recognise that the safety, welfare, and professional integrity of healthcare providers are integral to patient safety and quality of care, and that facilities must ensure safe and supportive working conditions for providers."	Provider welfare underpins patient safety; this aligns the Bill with the Health Act and the Occupational Safety and Health Act, 2007.	**Reject**
67		**Fatma Kasyoka Said**	Include principles on equity, patient-centred care, digital health governance, transparency, accountability, workforce development and continuous learning.	Key principles such as equity, patient participation and digital health are not expressly recognised. Stronger governance principles aligned with international best practice are required.	**Reject**
68	**Clause 5 – Responsibilities of the Cabinet Secretary**	**Confraternity of Patients Kenya (COFPAK)**	In clause 5(c)(iv), add the words "and patient" so that it reads "the healthcare provider's and patient experience".	Lived experience provides unique insights. Patients are constant in the continuum of care; healthcare workers may change shifts or workstations, but patients are present across the cascade of care.	**Accept**
69		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Kenya Union of Medical Laboratory Union**	Amend clause 5(a) to add the words "including staffing norms and standards". Insert a new 5(f) to provide; "liaise	Lack of adherence to staffing norms and standards, together with lack of job security, has been one of the greatest hindrances to the provision of	**Accept:** This is already provided for in the Bill.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
		& Association of Medical Laboratory Officers (Aidah Mercy et al.); Walter Lesaatin; Sheero M.	with the National Assembly and County Governments to ensure adequate budgetary allocation to health in line with local and international obligations." Insert a new 5(g): "Develop and enforce guidelines on terms and conditions for employment in the health sector."	quality healthcare.	
70		**George Okoth Osimbo**	In clause 5(a), insert the words "in consultation with the relevant Health Professional Regulatory Bodies and County Governments" after the word "protocols". Substitute clause 5(e) so that closure of a health facility is undertaken only on the recommendation of the Authority and the relevant regulatory body and after compliance with Article 47, except where there is an immediate threat to life or public health.	Staffing norms and quality standards directly affect regulated professions, so mandatory consultation is needed. Closure of a health facility affects the constitutional rights to property (Art. 40), fair administrative action (Art. 47), fair hearing (Art. 50) and access to healthcare (Art. 43).	**Reject**
71		**Kinyua Murithi**	In clause 5(e), delete all words beginning with "including" to the end of the clause.	The power to close non-compliant health facilities rests with the Quality Healthcare and Patient Safety Authority established under clause 26.	**Reject**
72	**Clause 6 – Responsibilities**	**Confraternity of Patients Kenya**	Amend clause 6(f) to read-	This guides and fosters enhanced activities on quality improvement	**Accept:** This is already addressed by the Bill.

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
	of county governments	**(COFPAK)**	"Maintain a county-level quality improvement and Patient Safety programme to address service gaps and monitor key performance indicators".	and patient safety.	
73		**Council of Governors (CoG)**	Introduce a new section entitled "County Quality Governance" to provide: "(1) Every county government shall establish appropriate governance arrangements for implementation of this Act within devolved health services. (2) The county quality governance framework shall — coordinate quality improvement programmes; oversee patient safety programmes; monitor quality indicators and health outcomes; promote clinical governance across all levels of care; coordinate learning from adverse events; support multidisciplinary quality improvement; and submit reports as prescribed under this Act. (3) County governments shall determine governance structures appropriate to their health systems provided they are consistent with national standards."	The Bill establishes robust national governance arrangements but provides no corresponding governance framework for county governments, despite counties being responsible for delivering health services from Level 1 to Level 5. The amendment strengthens implementation while respecting devolution and allowing counties flexibility, with county structures remaining subject to national standards.	**Reject**
74		**Kinyua Murithi**	Reword clause 6(e) to read:	Extending the authority to monitor quality in private and	**Reject**

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			"Monitor the quality of healthcare in all county health facilities in the county."	faith-based facilities extends the powers of county governments to policy and regulation, which is not provided for in the Constitution of Kenya, 2010.	
75		**George Okoth Osimbo**	Amend clause 6(e), by inserting the words "in collaboration with the Authority and the relevant Health Professional Regulatory Bodies" immediately after the words "health facilities".	Promotes coordinated oversight and avoids multiple, uncoordinated inspections by different agencies, consistent with Articles 6, 189 and 232 of the Constitution.	**Reject**
76		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Amend clause 6 to require mutual consultation between the Authority and County Executives before enforcement actions.	As drafted, the clause reduces county authorities to execution units, compromising the constitutional autonomy of devolved governance.	**Reject:** The concept of collaboration between the two levels of government is already addressed in the Constitution of Kenya.
77		**Kenya Union of Clinical Officers (KUCO)**	Insert an express cooperative-devolution clause. Clause 6 should recognise county responsibility for service delivery, HRH, financing, facility management and county quality programmes; national standards affecting county services should be developed and implemented through structured consultation with counties.	Articles 6(2), 186–190 and the Fourth Schedule; the Health Act; and the Intergovernmental Relations Act require consultation, cooperation and respect for the functional and institutional integrity of both levels of government.	**Reject:** This is already addressed in the Constitution.
78		**Kennedy Kinyua**	Amend the Bill to require the Cabinet Secretary and Authority to consult the Council of Governors, county health departments, professional regulators, patient	The Bill assigns substantial monitoring, reporting and implementation duties to counties without a joint standard-setting mechanism, minimum	**Reject**

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			organisations and training institutions before prescribing standards. Standards should be costed, level-specific and accompanied by an implementation plan and capacity support.	financing obligations or a differentiated implementation schedule, creating unfunded mandates and weakening county ownership of devolved health services.	
79		**Dr Ghalib Moseti Abdillahi**	Amend the Bill to require joint inspection with the county government for county facilities, consultation with the county before licensing or closure, and county representation on the Board.	Health services are a devolved function under Part 2 of the Fourth Schedule and counties operate the majority of facilities. The Bill imposes duties on counties under clause 6 while providing no county seat on the Board and no consultation before a county facility is licensed, rated or closed.	**Reject:** Registration, licensing and accreditation of health facilities is a function of the Authority under the Bill.
80	**Clause 8 – Right to safe and accessible health facilities**	**Confraternity of Patients Kenya (COFPAK)**	Amend clause 8(1) to read: "Every patient has the right to receive healthcare services in a safe, respectful, and accessible health facility."	Gives a human aspect to the section by adding respect alongside safety and accessibility.	**Reject**
81		**KELIN**	Rephrase clause 8(2)(c) to read: "provide reasonable modifications to enable accessibility by persons with special needs as stipulated in the Persons with Disabilities Act".	The Persons with Disabilities Act has a broader scope of modifications, covering physical and environmental access and communication support (ramps, toilets, elevators, entrances, signage and communication access).	This fosters active participation and shared decision-making between the recipient of care and healthcare providers.
82		**Kinyua Murithi**	In clause 8(1)(b), replace "Public Health Act" with "relevant laws".	Waste management is regulated through other laws such as the	**Reject**

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			In clause 8(1)(f), add a paragraph: "Implement measures to prevent medical errors".	Environmental Management and Coordination Act and the Radiation Protection Act. Medical errors are a persistent and potentially preventable risk; requiring facilities to establish preventive measures protects patient safety to currently recognised international standards.	
83	**Clause 9 – Right to care by a qualified healthcare professional**	**Kenya Medical Association (KMA)**	Insert a new paragraph in clause 9(2) providing that a healthcare provider should also be a member in good standing of the relevant recognised professional association.	Professional association membership provides an additional, complementary layer of peer accountability and continuing-education tracking alongside statutory licensure.	**Agree:** This is already addressed.
84		**Kenya Union of Clinical Officers (KUCO)**	Retain the clause but add that professional qualification, competence, licence status and lawful scope of practice shall be verified by the relevant statutory professional regulatory body.	The Bill itself recognises the regulator for qualifications and licensing; professional scope should follow the same coherent regulatory chain.	**Agree:** This is already addressed by the Bill.
85		**David Wekesa**	Retain, but expressly provide that qualification, registration, licensing and professional competence of medical laboratory personnel shall be determined by KMLTTB under Cap. 253A.	Potential duplication of verification and professional-authorisation decisions; the framework must not allow the Authority to independently determine laboratory professional competence.	**Agree:** This is already addressed by the Bill.
86	**Clause 10 – Right to**	**IDinsight Dignity Initiative**	Insert a new subsection to provide:	The Bill currently contains no consent requirement at all.	**Reject**

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	information and decision-making		"A healthcare provider shall obtain the informed consent of the patient, or of the patient's lawful representative where the patient lacks capacity, before undertaking any examination, treatment or procedure, save where the delay occasioned by seeking consent would endanger the life of the patient."	Consent should be sought as a conversation, not a form; in the submitter's survey, Kenyans ranked consent paperwork far below being listened to.	
87		**Kennedy Kinyua**	Add a subsection preserving the informed-consent framework under the Health Act and other laws, including accessible communication, supported decision-making, documentation, withdrawal and lawful emergency exceptions. Regulations should not lower existing consent protections.	The right to information does not expressly state that consent must be voluntary, informed, documented where appropriate and capable of withdrawal, and does not address supported decision-making, minors, persons lacking capacity, emergency exceptions or communication in a language the patient understands.	**Reject**
88	**Clause 11 / 16 – Right to be heard; complaints**	**Kennedy Kinyua**	Specify minimum contents of the complaint's mechanism: multiple accessible channels, acknowledgement and resolution timelines, confidentiality, non-retaliation, written reasons, appeal/escalation, preservation of records and referral of professional misconduct to the relevant council. Require Kiswahili, English and accessible formats with locally	A standard template alone will not guarantee accessible, timely and independent redress. The Bill sets no minimum response periods, escalation routes, assistance for persons with disabilities or protection of complainants and witnesses.	**Reject**

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			appropriate language support.		
89		**Pharmaceutical Society of Kenya (PSK)**	Insert the following provision: "Where a complaint concerns professional conduct, competence, scope of practice or fitness to practise, the Authority shall refer the matter to the relevant statutory regulatory body. The Authority shall retain jurisdiction over facility-level systems and quality failures. A person shall not be subjected to duplicate disciplinary proceedings in respect of the same professional-conduct issue."	Routing complaints according to the nature of the failure prevents double jeopardy, conflicting decisions and institutional mandate disputes, while preserving accountability for both facility systems and individual conduct.	**Reject:** The Bill already separates regulation of professionals from the regulation of health facilities
90		**Dr Geoffrey K. Maiyoh**	Insert a new Clause 16A immediately after clause 16 establishing a mandatory mediation and no-fault compensation mechanism as follows: "(1) There shall be established a Patient Safety Compensation Fund administered by the Authority. (2) Where a patient suffers an adverse event in a health facility, the facility shall, within 30 days of the event or complaint, refer the matter to a mediation panel comprising a healthcare professional, a legal officer, and a patient representative appointed by	The Bill provides for internal complaints and the Tribunal but no fast, no-fault compensation pathway. Norway's national no-fault Patient Injury Compensation system delivers fast payouts without proving negligence, reducing litigation by over 60%; Taiwan's compulsory mediation resolves over 60% of disputes in under 30 days at minimal cost. This would decongest the Tribunal and deliver faster justice to poor patients.	**Reject:** all complaints pertaining to matters covered by this Act will be determined by the Tribunal.

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			the Authority. (3) The panel shall make a no-fault compensation recommendation within 60 days of referral. (4) A patient who rejects the recommendation may proceed to the Tribunal under Part VI."		
91	**Clause 13 – Right to safe and quality care**	**Pharmaceutical Society of Kenya (PSK)**	In clause 13(2)(c), delete the words referring only to safe administration of medication and substitute the words: "safe selection, procurement, prescribing, transcription, preparation, storage, dispensing, administration, medication reconciliation, monitoring, pharmacovigilance and disposal of medicines."	Medicine-related harm may originate before or after administration from inappropriate selection, incorrect dosing, interactions, dispensing errors, failures at transitions of care and inadequate monitoring. The amendment makes medication safety an end-to-end obligation.	**Reject**
92	**Clause 14 – Right to safe and quality health products and technologies**	**Regulatory Affairs Professionals Society of Kenya (RAPSK)**	Rewrite clause 14(1) in full: "Every patient has the right to safe, quality and efficacious health products and technologies."	The clause omits the term "efficacious". This is currently the mandate statement of the Pharmacy and Poisons Board and needs to be captured in full.	**Reject**
93		**Tom Kauki**	Revise clause 14(1) to read: "Every patient has the right to safe, quality and efficacious health products and technologies."	The section as drafted does not provide for the right to efficacious health products, nor for provider responsibilities to report poor-quality, substandard or falsified products, nor for	**Reject:** the law on dispensation and disposal of health products and technologies is the Pharmacy and Poison Act which already addresses the concerns raised. The essence of clause 14 is to basically reiterate the

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			Add a new sub-section 14(2)(e) to provide: (e) every healthcare provider shall report poor quality health products and technologies to the relevant regulatory body in accordance with the Guidelines provided by the relevant regulatory body". Add subsection 14(2)(f) to provide: every healthcare provider shall report suspected substandard and falsified health products and technologies to the relevant regulatory body". Insert a new subsection 14 (2)(g) to provide: Every healthcare provider shall manage healthcare waste in an environmentally sound manner".	environmentally sound healthcare waste management.	rights of patients to quality health products
94		**Pharmaceutical Society of Kenya (PSK)**	In clause 14(2), insert the words "to the extent authorised by the written law and scope of practice governing that provider" immediately after the reference to a healthcare provider. Insert a new subsection recognising a patient's right to pharmaceutical care by a pharmacist registered	Prevents unintended expansion of prescribing, dispensing or administration rights and preserves profession-specific scopes of practice. Pharmaceutical care translates the right to safe medicines into concrete patient services.	**Reject**

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			under Cap. 244, including prescription review, medication reconciliation, identification and resolution of medicine-related problems, counselling, medicines optimisation and monitoring of outcomes.		
95		**Kinyua Murithi**	In clause 14(1)(a), add the words "Standard treatment guidelines or established national/international consensus standards" after the words "relevant laws". In 14(1)(b) insert the words "or permitted" immediately after the word "approved". In 14(1)(c) replace the word "Guidelines" with "regulations" and "body" with "bodies", to read: "… in accordance with regulations by the Cabinet Secretary in consultation with relevant regulatory authorities".	Laws do not define appropriate or rational use of medicines in sufficient detail; standard treatment guidelines provide the required detail. Use of unregistered products is permitted under Cap. 244 for named patients. Guidelines are not legally binding unless they restate specific law, and have been used to amend or repeal law in effect.	Reject
96		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Insert a clause subordinating technical product standards and pharmacy approvals to the Pharmacy and Poisons Act (Cap. 244).	Clause 14 overlaps with the statutory authority of the Pharmacy and Poisons Board under Cap. 244.	**Reject:** The Bill provides for a clearly delineated role between the Authority and Pharmacy and Poison Board.

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97		**Hadija Bisharo**	Amend the clause so that all diagnostic processing and verification is strictly overseen by KMLTTB-registered and licensed professionals.	Allowing non-laboratory professionals to manage and sign off advanced pathology tests, and permitting cross-profession reporting, invites misdiagnosis and medical litigation.	**Reject**
98		**Dr Joash Auka**	Insert a savings clause in Part IV confirming that the Authority's facility licensing does not derogate from sector-specific safety licensing (Kenya Nuclear Regulatory Authority) or professional scope-of-practice regulation by the relevant statutory council.	The High Court held in Kenyanya & 2 others v Kenya Nuclear Regulatory Authority [2026] KEHC 557 (KLR) that KNRA had usurped the mandate of the Radiographers Board of Kenya and ordered a transition of licensing functions to the Board. The Bill risks introducing a third overlapping regulator into a boundary the courts have only just settled.	**Reject:** The Bill clearly delineates health facility regulation and regulation of professionals. The role of the Authority is limited to registration, licensing and accreditation and inspection of health facilities.
99	**Clause 15 – Right to dignity and equity**	**IDinsight Dignity Initiative**	Insert a new paragraph (d) in clause 15(2) to read: "(d) be accompanied by a companion of the patient's own choosing during the receipt of healthcare services, save where the presence of a companion poses a documented risk to clinical safety."	Guaranteeing a companion of choice, including during childbirth, is in line with WHO recommendations. The evidence is robust and the cost negligible. One in five women in the Population Council's Heshima study reported disrespect or abuse during childbirth.	**Reject:** The provision is concerned with the right to dignity in treatment. The proposal does not address this right.
100		**Kinyua Murithi**	In clause 15(1)(b), add the words "residency or citizenship status" immediately after the word "ethnicity" and before "health	Residents and aliens in Kenya should have access to quality healthcare in fulfilment of Kenya's international obligations.	**Reject**

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			status".		
101	**Clause 17 – Patient rights charter**	**KELIN**	Recommend that in developing the Charter under clause 17(3), the Authority adopts the format and contents of the World Health Organization Patient Safety Rights Charter developed under the Global Patient Safety Action Plan 2021–2030.	Alignment with an internationally validated charter supports awareness for patients on quality healthcare.	**Accept**
102		**Kinyua Murithi**	In clause 17(1), replace "3" with "4" in the parenthesis.	Minor correction: the template is issued under clause 16(4).	**Reject**
103	**Clause 18 – Patient safety and quality assurance measures / scope of practice**	**Health Unions Caucus (KUCO/KCOA); KNUMLO; KUNAD; BCMGA; Scovia Adema; Judy Mso; Ken Ochoggia; Maramba Morena; Emmanuel Chiboya; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Amend the Bill by deleting the words "Director General" and replacing with the words "relevant regulatory body", to read: "A health facility shall — (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 relevant regulatory body."	Scopes of practice are currently developed by regulatory bodies as the tool used in regulation of practice. The Director-General sits on ALL the regulatory bodies as a board member; having the Director-General recommend the scope of practice to the Cabinet Secretary creates a conflict of interest, elevating one board member above the entire regulatory board by conferring veto powers on that office.	**Reject:** The Director General is the technical officer on health matters. The Director General sits on Boards as an ex-officio member and that does not in any way elevate him above the Boards served.
104		**Kenya Medical Association (KMA)**	Provide that scope of practice be prescribed by the respective professional regulatory body and gazetted by the Cabinet Secretary; or, in the alternative, that the Cabinet Secretary's determination	Scope of practice is a core professional-competence determination historically and appropriately made by the bodies that certified the underlying training; vesting it in the	**Reject** for reasons provided above

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			requires the concurrence of the relevant professional regulatory body.	Executive alone erodes professional self-regulation.	
105		**Dr Ghalib Moseti Abdillahi**	Amend clause 18(1)(c) to read: "(c) adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as prescribed by the respective statutory regulatory body established under the relevant written law;" In the alternative, insert the words "and with the written concurrence of the statutory regulatory body responsible for the cadre concerned" immediately after the words "Director General"	Scope of practice is the single most consequential determinant in health regulation: it decides who may perform which clinical procedure. Clause 18(1)(c) permits it to be altered by administrative instrument without the participation of the council that examined, registered and licensed the practitioner. This sits uneasily with the Bill's own amendment confining KHPOA to "the regulation of healthcare professionals" scope of practice being precisely that. Non-compliance attracts a fine of up to ten million shillings.	**Reject** for reasons provided above
106		**Pharmaceutical Society of Kenya (PSK)**	Delete clause 18(1)(c) and substitute the following clause: "ensure that every healthcare provider employed or contracted by the facility practises within the scope of practice prescribed or recognised by the statutory regulatory body established under the written law governing that profession."	Professional scopes, competence and standards should remain with the regulator created by Parliament for the relevant profession. This avoids conflicting scopes and protects public safety.	**Reject** for reasons above

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107		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend clause 18(1)(c) [cited as 19(1)(c)] to read: "(c) adhere to the scope of practice for healthcare providers employed or contracted in health facilities as prescribed by the relevant regulatory bodies and approved by the Cabinet Secretary on the recommendation of the Director-General."	Regulatory bodies develop and maintain professional scopes; explicitly referencing them upholds professionalism, ensures an up-to-date scope and aligns with enabling laws and standards.	**Reject** for reasons provided above
108		**Kinyua Murithi**	In clause 18(1)(c), add the words "in consultation with the relevant regulatory authorities" after "Director General". Delete clause 18(2).	Scope creep is a major problem between and within regulatory bodies; involving regulators reduces litigation since the DG may not be accepted as an unbiased arbiter. Safety and quality standards are broad, progressive and aspirational; criminalising non-adherence to all such standards, including minor mishaps causing no harm, is inappropriate. The Authority should investigate and sanction under clause 68; the ODPP, DCI and regulatory bodies retain powers over criminal negligence and the judiciary over torts.	**Reject** for reasons provided above
109		**Dr Maria Ogaya Gerald**	Amend clause 18(1)(c) to clarify that the Cabinet Secretary shall only prescribe quality standards and implementation mechanisms, while	Scope of practice is established by profession-specific statutes and regulatory councils based on education, competency,	**Reject**

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			scope of practice remains the responsibility of the respective statutory professional councils. Expressly recognise profession-specific scopes of practice and ensure the Bill regulates healthcare systems rather than redefining professional competence.	internship, postgraduate training and licensure. Allowing the Cabinet Secretary to prescribe scope through regulations may undermine statutory mandates and permit expansion or restriction of professional practice without parliamentary amendment of the parent Acts. Repeated reference to "healthcare providers" without distinguishing registered medical practitioners from other cadres risks implying equivalence of professional authority despite differing training, legal responsibilities and statutory scope.	
110		**Kenya Union of Clinical Officers (KUCO)**	Replace with the following: "A health facility shall adhere to the scope of practice applicable to each healthcare profession as prescribed by the Cabinet Secretary on the recommendation of the relevant statutory professional regulatory body, following consultation with affected stakeholders."	Scope determination is vested by Parliament in profession-specific statutes: the Clinical Officers Act, Nurses and Midwives Act, Pharmacy and Poisons Act, MPDA, MLTT Act, PHOTC Act and Nutritionists and Dieticians Act.	**Reject** for reasons provided above
111		**Kennedy Kinyua**	Replace clause 18(1)(c) with the following clause: "adhere to the scope of practice	Scope of professional practice is already governed by profession-specific statutes and councils.	**Reject** for reasons provided above

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			applicable to each healthcare professional under the relevant professional regulatory law."		
112		**Chacha Omahe**	Delete clause 18(2) (criminal penalties for quality assurance failures) or, in the alternative, amend it to replace criminal penalties with a graduated enforcement framework beginning with corrective orders, followed by administrative sanctions, reserving criminal liability for gross negligence or wilful misconduct only.	Severe criminal penalties will encourage cover-ups, discourage voluntary error reporting and undermine patient safety mechanisms such as MPDSR. International best practice (the NHS "Just Culture" framework) demonstrates that learning-oriented systems produce better safety outcomes than punitive ones.	**Reject:** fines are necessary for compliance with the obligations established under this clause.
113		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Amend clause 18(2) so that the penalty reads: "a fine not exceeding one million shillings or imprisonment for a term not exceeding two years, or to both."	To rationalise the fine and jail term.	**Reject:** The fine of ten million is necessary to enforce compliance with the obligations under this clause.
114		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Add a proviso protecting employees from liability where non-compliance stems from documented resource shortages.	Clause 18 holds facilities liable for safety compliance under threat of a ten million shilling fine but lacks an indemnity safeguard for staff working in under-resourced public health facilities.	**Reject**
115		**IDinsight Dignity Initiative**	Insert a new paragraph in clause 18(1) to provide:	Practice changes treatment; posters do not. In interviews with health workers in western Kenya,	Reject

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			"(e) institutionalise respectful, person-centred care, including through the visible and personal endorsement of respectful care by the person in charge of the health facility."	senior clinicians decided whether new practices reached the ward. Visible endorsement by the facility in-charge carries the strongest evidence.	
116		**Health Unions Caucus (KUCO/KCOA); KNUMLO; KEHPHPU; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Include health workers' rights to safety and a conducive working environment in Part II, in line with the Occupational Safety and Health Act, 2007 and mental health legislation.	Health workers' rights and safety are central to quality of care and patient safety, and align the Bill with other regulatory Acts.	**Reject:** The health workers rights are already provided for under the Employment Act and the occupational safety and Health Act.
117	**Clause 20 – Evidence-based practice / clinical guidelines**	**Kenya Medical Association (KMA)**	Require that clinical guidelines be developed in consultation with, and reviewed by, relevant professional regulatory bodies and professional associations including specialist medical associations; be evidence-based and locally adapted; and be reviewed at intervals not exceeding three years. Where guidelines developed by professional associations require Director-General approval before carrying legal force, make this explicit with a defined approval timeline and criteria.	These guidelines define the standard of care against which individual doctors are judged, including in negligence and disciplinary proceedings; professional input is essential to their clinical validity and legitimacy.	**Agree** however the Director General is constitutionally obligated to facilitate public participation in when coming up with guidelines or regulations which addresses the concerns raised by the stakeholder.
118		**Dr Ghalib Moseti**	Amend clause 20(2) to require	These guidelines acquire	Agree for reasons above

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		Abdillahi	development of guidelines "in consultation with the relevant statutory professional regulatory bodies, specialist professional associations, training institutions and county governments", and review at intervals not exceeding three years. Insert a new subsection providing that a documented departure from a clinical guideline, reasonably justified by the clinical circumstances of the patient, shall not of itself constitute non-compliance.	regulatory force through clause 13(2)(b) (adherence becomes a patient right) and clause 59(d) (conformity a condition of accreditation). Guidelines with that effect should not be issued by a single office without consultation. A guideline should not displace clinical judgement where a practitioner reasonably departs from it in the patient's interests — a situation that arises routinely in obstetric emergency care.	
119		**Kenya Union of Clinical Officers (KUCO)**	Retain national clinical-guideline coordination, but add that where a guideline affects a profession's scope, competency, medicines authority, procedures or professional standards, it shall be developed in consultation with, and with the concurrence or recommendation of, the relevant statutory regulatory body.	Guidelines that bind professional practice should be produced with the concurrence of the regulator Parliament created for that profession.	Agree for reasons above
120	**Clause 21 – Safety and risk management / incident reporting**	**Dr Geoffrey K. Maiyoh**	Amend clause 21(5) by inserting the words "and no healthcare provider shall be subjected to disciplinary action, demotion, dismissal, or any form of retaliation solely for making a good-faith report under this section." immediately after the words "anonymous reporting":	Clause 21(3) requires providers to report risks and 21(5) allows anonymous reporting, but the Bill does not protect a provider from retaliation for a good-faith report. Japan and Taiwan operate "no-blame" reporting systems for near-misses and adverse events,	**Reject**

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				increasing reporting rates by over 300% and reducing medical errors by 30 – 40% over a decade.	
121		**Dr Ghalib Moseti Abdillahi**	Insert a new section providing that a patient-safety or near-miss report made in good faith shall be treated confidentially, be protected from retaliation, be used primarily for quality improvement, be de-identified before publication, not constitute an admission of negligence or liability, and not be used as the sole basis for disciplinary action. The protection should not extend to fraud, deliberate concealment, intentional harm, gross negligence or criminal conduct.	Reporting systems fail where reports can be used against the reporter in disciplinary, civil or employment proceedings. Anonymity under clause 21(5) is not a substitute for legal protection and is unavailable in a small unit where the reporter is readily identifiable.	**Reject**
122		**Kennedy Kinyua**	Create a statutory just-culture framework. Provide that "A patient-safety report made in good faith shall be confidential and shall not, by itself, form the basis of disciplinary or civil liability. This protection does not apply to fraud, wilful misconduct, gross negligence, criminal conduct or concealment of a serious continuing risk."	If near-miss reports can readily be used to punish staff, reporting will be suppressed. The clause also risks duplicate reporting to the Authority, county systems, the Digital Health Agency, pharmacovigilance bodies and professional regulators.	Reject

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			Also provide fo a single interoperable reporting pathway; de-identify learning reports; restrict secondary use; separate learning reviews from disciplinary investigations.		
123		**Kenya Medical Association (KMA)**	Establish a confidential, non-punitive incident reporting system for adverse events and near misses, supported by root cause analysis and tracked corrective action.	A blame-free reporting culture promotes learning, transparency and continuous improvement in patient safety.	Reject
124		**Council of Governors (CoG)**	Insert a new section to provide; "Just Culture": "Health facilities (primary care networks) shall establish a system that promotes reporting and learning from patient safety incidents while ensuring accountability for grossly negligent or intentional misconduct. Regulations shall distinguish between human error, at-risk behaviour and grossly negligent conduct when responding to patient safety incidents." Insert a further section on organizational learning to read: "Every serious adverse event shall undergo Root Cause Analysis. Health facilities shall implement	The WHO Global Patient Safety Action Plan 2021–2030 treats transparency, openness and a 'no-blame' culture as a distinct strategic priority and sets a voluntary global target for no-blame reporting policies. Distinguishing human error, at-risk behaviour and grossly negligent conduct avoids the chilling effect on reporting that blanket-liability regimes have produced elsewhere. Reporting duties not paired with mandated root cause analysis and corrective action have proved ineffective internationally at reducing avoidable harm.	

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			corrective actions arising from such analysis and periodically share lessons learned for continuous improvement of patient safety."		
125		**Pharmaceutical Society of Kenya (PSK)**	Replace clause 21(1)(b) with with the following: "Establish systems for the safe selection, procurement, prescribing, transcription, storage, preparation, dispensing, administration, medication reconciliation, monitoring, pharmacovigilance and disposal of medicines and other health products, integrated with the Comprehensive Integrated Health Information System where applicable." Also insert new subsections requiring every facility to establish an integrated medication-safety system (prescription review, medication reconciliation at admission/transfer/discharge, high-alert and look-alike/sound-alike medicine controls, medication-error and ADR reporting and learning, antimicrobial stewardship, medication-use evaluation, patient counselling, pharmacovigilance and safe pharmaceutical-waste	The amendment assigns technical accountability and converts medication safety into measurable facility systems. It strengthens prevention, reporting and learning while retaining PPB's professional and medicines-regulation mandate.	Reject

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			management); require facilities providing inpatient, surgical, emergency, intensive-care, oncology, paediatric or maternity services to designate a registered pharmacist for technical oversight; and require standards under this section to be developed by the Authority in consultation and concurrence with the Pharmacy and Poisons Board.		
126		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	In clauses 21(2) and 22(2), insert the words "in a manner proportionate to its category and level of care as prescribed in Regulations," immediately after the words "Every health facility shall".	The proportionality principle in clause 22(1)(c) binds only the framework to be developed by the Cabinet Secretary; it does not qualify the obligations that take effect on commencement. A structured quality assurance programme with peer review presupposes a quality officer, a health records function and a professional peer group.	Reject
127		**Lydia Nyawira Mburia**	Develop an elaborate healthcare and patient safety mitigation, prevention, corrective and risk-management plan outlining remedial measures for health emergencies in all health facilities; and formulate comprehensive home-based care plans for follow-up of all patients after discharge.	Risk management under Part II should extend to structured emergency preparedness and post-discharge continuity of care.	

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128	**Clause 22 – Quality improvement**	**Kenya Medical Association (KMA)**	Require every facility to implement a continuous quality improvement programme comprising clinical audits, morbidity and mortality reviews, patient satisfaction surveys, infection-prevention audits and documented quality improvement plans, overseen by a multidisciplinary Clinical Governance Committee. Expand the clause 22(1)(a) benchmarks to include patient safety and timeliness of care alongside clinical outcomes and efficiency, and reflect staffing capacity, not just resource availability, in clause 22(1)(c).	Effective quality improvement requires structured monitoring, evaluation and corrective action under clear governance, not ad hoc activity. Of the internationally recognised quality dimensions (WHO/OECD/World Bank; IOM), clause 22 as drafted omits safety and timeliness, the two most directly tied to preventable patient harm.	
129		**Council of Governors (CoG)**	Introduce a new section entitled "Clinical Governance" to provide: "Every health facility (or primary healthcare network to accommodate smaller facilities) shall establish and maintain an appropriate clinical governance framework to ensure continuous improvement in the quality, safety, effectiveness and patient-centredness of healthcare services. The framework shall include — clinical leadership; patient safety; quality improvement; clinical audit; peer review; evidence-based practice; workforce	Clinical governance is internationally recognised as the foundation of quality healthcare and integrates the various quality provisions of the Bill into a coherent framework. This is consistent with the WHO Global Patient Safety Action Plan 2021–2030, which identifies good governance frameworks and clinical and managerial leadership capacity as core strategic priorities.	Reject

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			development; patient participation; and monitoring of quality indicators."		
130		**IDinsight Dignity Initiative**	Delete clause 22(1)(a) and substitute with the following: "(a) setting benchmarks for patient satisfaction, including patients' experience of dignity and respectful care, clinical outcomes, and service efficiency;". Further insert a new subsection to provide: " "The framework under subsection (1) shall provide for the continuous collection of patient satisfaction data and its publication at least quarterly, disaggregated by county and by sex, age, disability and socio-economic status."	One annual number cannot guide improvement. County results matter most: in Kenyan survey research, where you live predicts how respected you feel, and a national average hides what the House of the counties exists to see.	Reject
131		**Dr Maria Ogaya Gerald**	On clause 22(1)(b), include provisions requiring national and county governments to provide adequate financing and implementation support before imposing performance obligations. Amend clause 22(2)(b), amend to expressly include maternal, newborn, child and adolescent	Requiring facilities to reduce disparities in access without commensurate financing, staffing and infrastructure may disproportionately burden public facilities and distort pricing or service delivery in private facilities. The provision mentions maternal healthcare but does not explicitly recognise child health,	Agree

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			health.	despite children constituting a vulnerable population with distinct needs.	
132		**Kennedy Kinyua**	On clause 22(4), use graduated compliance: immediate exclusion from the Social Health Insurance Fund should be reserved for an imminent and serious patient-safety risk; other facilities should receive a time-bound improvement plan, technical support and proportionate conditions while continuity of essential services is protected.	Making compliance the basis of accreditation and access to the Fund could abruptly exclude essential public or rural facilities whose deficits arise from infrastructure and workforce constraints. Patients may be punished for system underinvestment.	Accept: This is already provided for in the Bill
133		**Council of Governors (CoG)**	Insert a provision requiring health facilities to establish mechanisms for meaningful patient participation in quality improvement initiatives.	Modern quality improvement recognises patients and communities as partners in designing, evaluating and improving healthcare services. Patient and family engagement is one of the seven strategic objectives of the WHO Global Patient Safety Action Plan 2021–2030.	Accepted
134		**Health Unions Caucus (KUCO/KCOA); BCMGA; Chacha Omahe; Scovia Adema**	Amend clauses 22(4) and 70(c) to require that performance targets account for systemic constraints (staffing levels, supply chains, infrastructure) and that penalties apply only where the facility has been provided with adequate resources and a reasonable	Many public facilities face chronic understaffing, supply shortages and infrastructural gaps beyond their control. Penalising them risks worsening morale, accelerating staff exodus and even service avoidance. Quality outcomes depend on factors	Agree however the concerns can best be addressed through regulations.

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			remediation period.	beyond facility control, including social determinants of health.	
135	**Clause 23 – Training and competency**	**Kenya Medical Association (KMA)**	Include mandatory continuing professional development, competency-based assessment, patient-safety training, and teamwork and communication education for healthcare workers.	Continuous professional development is essential to maintain competence and improve patient outcomes; competency assessment and CPD are not currently linked to patient safety.	Agree however the regulation of health professionals is left to the respective professional bodies.
136		**Kennedy Kinyua**	Expand clause 23 to cover competency-based induction, continuing professional development, emergency preparedness, simulation where appropriate, supervision of interns and students, and protected training time; require consultation with health-training institutions and professional councils.	The clause limits periodic training duties to counties and facilities without linking training to CPD, competency assessment, supervision of trainees or accredited providers.	Agree however the concerns of the stakeholder can be best addressed through regulations.
137		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Amend clause 23 to make the provision of regular patient-safety training a mandatory employer obligation.	The clause requires verification of staff qualifications but fails to guarantee regular, employer-funded training on updated safety guidelines and protocols.	Agree however the concerns of the stakeholder are sufficiently addressed.
138		**David Wekesa**	Delete any provision empowering the Authority to prescribe professional competency requirements or professional qualifications for laboratory personnel; retain facility-level competency systems only.	KMLTTB has statutory responsibility for professional training, qualifications and regulation of professional competence. Generic Authority competency standards could overlap with profession-specific	Agree however the Bill already separates health professionals regulation from health facility regulation.

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				competency requirements, creating uncertainty over who determines whether a laboratory professional is competent to practise.	
139	**Clause 24 – Professional indemnity**	**Pharmaceutical Society of Kenya (PSK)**	Amend the clause to provide that a health facility shall obtain and finance adequate institutional and vicarious-liability cover for its employees, interns and trainees, without prejudice to individual professional-indemnity cover required by a statutory regulator or written law.	The clause may make each employee, intern or contracted provider personally responsible for obtaining indemnity cover even where the facility bears institutional and vicarious liability. The amendment protects patients' access to compensation while avoiding an unfair transfer of institutional risk to employed staff.	Accepted: The Bill already requires the employer to take out a professional indemnity cover.. a
140		**Dr Ghalib Moseti Abdillahi**	Clarify that a facility shall insure itself against institutional liability and shall provide indemnity for salaried healthcare professionals acting in the course of employment; that interns, trainees and students shall be covered by the training institution or employing facility; and that individual practitioners remain responsible for cover relating to independent private practice.	The provision is welcome but ambiguous as to who bears the cost. It should not permit an employer to transfer the cost of institutional liability to salaried healthcare workers, nor leave interns, registrars and students without cover.	Agree. This is already covered in the Bill
141		**Kennedy Kinyua**	Clarify minimum cover, responsibility for premiums, vicarious liability, tail cover and	The clause may require overlapping facility and individual cover and does not	Reject

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			treatment of public facilities and trainees; permit pooled public-sector indemnity or approved risk-retention arrangements; require an affordability and insurance-market assessment before commencement.	address public officers, students, interns, volunteers, locums, visiting specialists, telemedicine, or occurrence-based versus claims-made cover. Mandatory cover may increase service costs or leave gaps where insurance is unavailable.	
142		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Insert a transitional "Indemnity Framework" clause to provide: "Pending enactment of a comprehensive indemnity framework developed through public participation, no provision of this Act shall impose new indemnity obligations on healthcare workers. The Authority shall, within twelve (12) months of commencement, convene a stakeholder consultation process including professional associations, regulatory councils, trade unions, insurers and other relevant parties to develop a legal instrument defining indemnity mechanisms, covering scope, funding arrangements, insurance or protection schemes, and dispute-resolution processes. Until such instrument is enacted, any attempt to impose indemnity requirements	Imposing indemnity obligations without a clear legal framework may expose healthcare workers to undue liability or uncertainty. A transparent, consultative process ensures any indemnity regime balances patient protection with provider security and respects collective bargaining and regulatory standards.	Reject

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			under this Act shall be suspended."		
143	**Clause 25 – Duties of the patient**	**Kennedy Kinyua**	Delete clause 25(b) and replace it with a duty to participate in care and communicate decisions honestly, without limiting the right to refuse or withdraw consent. Replace clause 25(f) with a requirement that the provider document informed refusal and offer a safe discharge/referral plan. Expressly state that failure or refusal to sign does not extinguish any constitutional or statutory right. The clause may be worded as follows: "A patient shall, to the extent reasonably possible, participate in decisions concerning care and communicate acceptance or refusal of recommended treatment. A refusal shall be documented after appropriate counselling, but shall not relieve a provider or facility of any duty imposed by law."	The duty to "adhere to medical advice and treatment" conflicts with informed refusal and bodily autonomy. Requiring a patient to sign a discharge certificate or release of liability may be coercive and could be used to defeat legitimate claims. A signature does not cure inadequate counselling or unsafe discharge.	Reject
144		**Kenya Medical Association (KMA)**	On clause 25(f), require documented informed refusal consistent with section 8 of the Health Act, 2017, with express confirmation that a patient's failure to fulfil their duties under this	A bare liability-release signature protects the facility rather than the patient and does not reflect genuine informed refusal.	Reject: the health Act already sufficiently addresses the issue.

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			section is not a ground for withholding emergency or medically necessary care.		
145	**Clauses 26–27 – Establishment and functions of the Authority**	**Confraternity of Patients Kenya (COFPAK)**	Add to the functions of the Authority, the power to; "Provide technical support and issue safety and quality improvement directives where required."	Adds a collaborative function to improving patient safety, aligned with Strategic Objective 5 of the WHO Global Patient Safety Action Plan (inspire, educate and skill health workers to contribute to the design and delivery of safe care systems).	Reject: The concerns of the stakeholders are already sufficiently addressed in the Bill.
146		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Amend the functions of the Authority as follows: delete the word "regulate" so that paragraph (a) reads "guide the development of health facilities' infrastructure"; delete the words "register" and "license" so that paragraph (b) reads "accredit health facilities"; delete paragraph (c); amend paragraph (j) to read "maintain a master register of all accredited health facilities"; and delete paragraph (l).	To strengthen the quality assurance framework and make the Authority an oversight body; to provide a two-tier quality assurance framework in which the relevant regulatory body registers and licenses while an independent body verifies and accredits; and to avoid conflict with other laws.	

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147		**Pharmaceutical Society of Kenya (PSK)**	Insert a new subsection to provide as follows: "In exercising its functions, the Authority shall not regulate the registration, licensing, professional conduct, competence, scope of practice or fitness to practise of an individual healthcare professional, or replace specialised regulation of premises, products or services vested by written law in a statutory regulatory body."	The Authority should regulate facility-wide systems and quality outcomes while statutory regulators retain professional and specialised technical mandates. Clear boundaries reduce duplication, contradictory orders and regulatory litigation.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
148		**Dr Ghalib Moseti Abdillahi**	Insert a new provision after clause 27 to provide: "For the avoidance of doubt, the Authority shall regulate health facilities, healthcare systems and institutional quality. The Authority shall not register, license, determine the scope of practice of, investigate professional misconduct by, or discipline an individual healthcare professional, and such functions shall remain vested in the relevant statutory professional regulatory body."	The Bill does not confine itself to institutions. Clause 18(1)(c) places scope of practice with the Cabinet Secretary; clause 20(2) vests clinical guideline development in the Director-General alone; clause 73(2)(b) directs inspections to assess provider competency; clause 84(4) subjects council decisions to a Tribunal on which they are not represented. Each concerns the regulation of persons, not premises.	Reject: for reasons provided above
149		**George Okoth Osimbo**	Amend the functions clause so that: registration, licensing and accreditation of facilities is done "in consultation with the relevant Health Professional Regulatory	Registration, licensing and accreditation of facilities directly affect the practice of regulated professions. Inspection of specialised services such as	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities

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			Bodies and in accordance with the applicable written laws governing health professions"; Substitute the conduct-regulation paragraph with; "regulate the administrative and institutional conduct of health facilities in relation to quality of healthcare, without prejudice to the statutory mandate of Health Professional Regulatory Bodies to regulate the professional conduct of healthcare practitioners"; Provide that inspections are conducted "in collaboration with the relevant Health Professional Regulatory Bodies where the inspection concerns specialised professional services"; Also amend to provide that monitoring and evaluation is done "through coordinated inspection mechanisms"; Also amend to provode that internship and training accreditation is done "in consultation with the relevant Health Professional Regulatory Bodies responsible for approving internship and training	medical laboratories, radiology, pharmacy and clinical practice requires technical expertise vested in the respective statutory regulators. Approval of internship and clinical training centres is already a statutory responsibility of the professional regulatory bodies. Residual powers as drafted are broad and may be interpreted as expanding the Authority's mandate into areas already regulated by statute.	

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			centres"; standards advice is "developed in consultation with the relevant Health Professional Regulatory Bodies"; and residual functions carry a proviso that "such functions shall not duplicate or derogate from the statutory mandates of Health Professional Regulatory Bodies established under written law".		
150		**Kenya Union of Clinical Officers (KUCO)**	Restructure clause 27 to limit the Authority principally to independent quality accreditation, national quality ratings and benchmarks, system-wide patient-safety oversight, cross-regulatory coordination and capacity building. Registration, licensing and professional conduct should remain with the legally competent regulator or authority.	Creates a true two-tier quality model: statutory registration/licensing plus independent quality verification and accreditation. Avoids one body being registrar, licensor, inspector, accreditor and enforcer simultaneously.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
151		**Lab Medicine Society of Kenya (LMSK)**	Insert a new clause to provide that: "The Authority shall exercise the functions in paragraphs (b), (e), (f), (g) and (h) in respect of specialised diagnostic and laboratory services in collaboration and consultation with the relevant statutory regulatory body."	The Authority may register, license, accredit, inspect and enforce against medical laboratories with no statutory obligation to involve KMLTTB. These provisions collectively centralise regulation for all health facilities including medical laboratories with no carve-out for facilities and professionals	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities

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			In the alternative, delete clauses 26–27, Part IV (ss.42–71) and clause 100 read with the Second Schedule insofar as they apply to medical laboratories regulated under Cap. 253A.	regulated under Cap. 253A.	
152		**Dr Maria Ogaya Gerald**	Clearly define the Authority as a coordinating and oversight body rather than a parallel regulator.	Several functions assigned to the Authority appear substantially similar to functions already exercised by KMPDC and other statutory councils, particularly regarding inspection, licensing oversight and professional standards.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
153		**Victor Osoo**	Delete the registration, licensure and accreditation function; strengthen the current laws and institutions that regulate different practices in healthcare.	This function is already performed by different regulators and its duplication will confuse and overburden the industry.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
154		**KELIN**	Highlight in practice the distinct mandates of the proposed Authority and the Kenya Health Professions Oversight Authority (KHPOA), established under Part 6 of the Health Act, 2017.	The proposed Authority seemingly mirrors the mandate of KHPOA. Clarity avoids duplication, reduces friction in implementation and enables Kenyan residents to know where to address their complaints.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
155		**Kenya Union of Clinical Officers (KUCO)**	The preferred option is to strengthen and rationalise the existing Health Act/KHPOA framework. If Parliament retains the new Authority, it should expressly	Health Act already establish KHPOA; State-corporation rationalisation policy militates against maintaining two overlapping bodies.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
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			rationalise the overlapping KHPOA functions and avoid maintaining two quality-oversight institutions with unclear boundaries.		
156		**Kenya Medical Association (KMA)**	On clause 27(h) read with sections 33–34 of the Social Health Insurance Act, 2023, insert a mandatory memorandum of understanding or joint standard between the Authority and the Social Health Authority.	The Authority accredits facilities for SHIF empanelment while the Social Health Authority separately empanels them, with no statutory coordination mechanism. This prevents conflicting requirements or delay in empanelment, which would directly affect patients' access to SHIF-funded care.	Reject
157		**Kennedy Kinyua**	Insert an objects-and-mandates provision to provide as follows: "In performing its functions, the Authority shall not assume a function assigned by written law to a professional regulatory body, county government, the Digital Health Agency or the Social Health Authority, and shall establish coordinated procedures that avoid duplicate applications, inspections, reporting and fees."	The definition of "health facility" imported from the Health Act as proposed to be amended extends to mobile and digital platforms, ambulances, outreach programmes, pharmacies, laboratories and mortuaries. Without an express boundary, the Authority's functions overlap with county approvals, the Digital Health Agency, the Social Health Authority and professional councils.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
158		**Fatma Kasyoka Said**	Expand the Authority's statutory functions to include healthcare quality research, national quality indicators, digital health	Functions currently focus primarily on regulation and oversight. A modern quality authority must be capable of	Reject

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			governance, healthcare workforce development, performance benchmarking and patient experience assessment.	supporting continuous health-system improvement.	
159		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend the functions/governance clause to provide: "In the event of any overlap or potential conflict between the mandates of the Authority and those of established professional regulatory bodies or other sector regulators, the independent regulatory body's statutory mandate shall prevail. The Authority shall, within six months of enactment, enter into formal memoranda of understanding with each relevant regulatory body to define coordination mechanisms, information-sharing protocols, and respective roles, ensuring that the Authority's activities do not infringe upon or subordinate the regulatory bodies' independence."	Independent regulatory bodies hold statutory mandates which must not be undermined by Authority powers. Clear mandate precedence prevents conflicts, protects professional autonomy and maintains stakeholder trust.	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities
160		**Kenya Medical Association (KMA); Dr Ghalib Moseti Abdillahi; Dr Royronald Ochieng Ongong'a;**	Insert a statutory joint standards coordination committee between the Authority and the relevant professional regulatory bodies for any determination of standards, guidelines or scope of practice	The Bill creates parallel regulatory tracks — the Authority for facilities and the existing councils for individual practitioners — with no mechanism to coordinate. This	Reject: The Bill adequately separates the regulation of health professionals from the regulation of health facilities

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		Daniel Kitunga	binding on both; and require memoranda of understanding addressing information sharing, joint inspection, referral of complaints, investigation of adverse events, facility closure, enforcement and the avoidance of multiple sanctions for the same conduct.	prevents doctors and facilities being subject to conflicting or uncoordinated directives from two separate regulators.	
161	**Clause 28 – Powers of the Board (fees)**	**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Delete clause 28(2)(f). In the alternative, amend it to read: "levy or charge fees for the services rendered by the Authority, in accordance with Regulations made under section 93."	The Bill establishes two routes to the same power. The Regulations route carries publication, consultation and parliamentary scrutiny; the Board route carries none. Under clause 28(2)(f) fees may be set by resolution, without publication, consultation, ceiling or differentiation by facility level. A facility is liable to three separate charges — registration, annual licence and accreditation. Where a statute provides two routes to the same power, the route requiring no instrument will in practice be the route used.	Reject
162		**Kenya Medical Association (KMA)**	Require all fees to be set exclusively through Regulations under clause 93 following at least thirty days' public and stakeholder consultation, scaled to facility size and category, capped by Regulation and grounded in a transparent cost-recovery methodology.	The Board's fee-levying power is open-ended, with no statutory cap, scaling or public consultation requirement. Unchecked fee-setting risks escalating compliance costs without accountability.	Accept: The itemization of the fees to be charged will be provided for in regulations. a

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
No.	**CLAUSE**	**STAKEHOLDER**	**PROPOSED AMENDMENT / COMMENT**	**RATIONALE**	**COMMITTEE RESOLUTION**
163		**Dr Maria Ogaya Gerald**	Harmonise fees across regulators and prohibit duplicate charges for substantially similar services.	Existing professional regulators already levy fees for licensing, accreditation and inspections. Additional fees increase the regulatory burden and the cost of healthcare.	This is noted by the committee
164		**Kenya Medical Association (KMA)**	Insert a new provision exempting a health facility licensed under this Act from any county single business permit, trade licence fee, or levy of a similar nature in respect of the operation of health services at that facility, without prejudice to county rates or charges of general application not specifically directed at the facility as such.	Layering a national health-facility licence and a county single business permit on the same activity is an unnecessary duplicate compliance burden, and is in tension with Article 209(5), which restricts county revenue-raising from prejudicing the national mobility of services, and Article 191, which gives national legislation priority where county action would be prejudicial to the health interests of Kenya as a whole.	Reject: Health function is exercised at both the national and county levels and therefore the county governments powers to issue single business permits cannot be taken away through this legislation.
165	**Clause 29 – Board of Directors of the Authority**	**Confraternity of Patients Kenya (COFPAK)**	Amend clause 29(1) to include: "One person appointed by the Cabinet Secretary from a nationally-recognised patient safety advocacy organisation to represent the interests of patients."	There is no explicit patient representative or patient advocacy organisation on the Board. A "consumer rights body" is not synonymous with a patient representative — consumer rights bodies deal with unfair trade practices, defective products, misleading advertising and consumer contracts, while patient safety/advocacy bodies deal with medical errors, adverse	Agree

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				events, patient rights, quality of care, informed consent and patient engagement. The public representative may not have lived experience, interest or expertise in patient rights, patient safety or healthcare quality.	
166		**KELIN**	Amend to provide for "One person nominated by civil society in the health sector appointed by the Cabinet Secretary to represent the public interest."	There is no single body responsible specifically for consumer rights in the health sector and there may be difficulty in reaching consensus on how the appointment is made. The body affiliated with consumer rights in Kenya does not deal with health as a single issue and may lack the required specialised capacity.	Reject: Board composition is governed by the Mwongozo guidelines and therefore an addition of another member will lead to bloating of the board.
167		**Kenya Medical Association (KMA)**	Amend clause 29(1) to include: "one person nominated by the Kenya Medical Association and appointed by the Cabinet Secretary".	Facilities bearing the direct compliance burden of the Act (registration, licensing, accreditation, inspection, penalties) require guaranteed, named representation of the country's largest association of practising doctors and facility operators, not a generic and discretionary nomination.	Reject for reasons given above
168		**Dr Ghalib Moseti Abdillahi**	Amend clause 29(1) to provide named seats for: a nominee of the Kenya Medical	A single collective seat cannot represent KMPDC, the Nursing Council, the Pharmacy and Poisons Board, the Clinical	Accept however the clause already provides for a nominee of statutory regulatory bodies.

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			Practitioners and Dentists Council; a nominee representing nursing and midwifery; a nominee representing pharmacy, laboratory and allied health professions; a nominee of the Council of County Governors; and a nominee representing public, private and faith-based health facilities. Professional nominees should be appointed from names formally submitted by the bodies concerned rather than selected at the discretion of the Cabinet Secretary.	Officers Council, KMLTTB, the Physiotherapy Council and the remaining allied health regulators, whose interests are neither identical nor always aligned. The Board determines facility categorisation, quality standards, performance ratings and, through accreditation, access to the Social Health Insurance Fund, and may close facilities — decisions with direct clinical consequence.	
169		**Pharmaceutical Society of Kenya (PSK)**	Amend the composition of the Board to include (a) one person nominated by the Pharmacy and Poisons Board; and (b) one pharmacist registered under Cap. 244 and nominated by the Pharmaceutical Society of Kenya, with at least ten year' experience in pharmaceutical care, medication safety, medicines regulation or health-system quality. Provide that nominees should collectively reflect the diversity of healthcare professions and the public and private health sectors.	One member is expected to represent all statutory health regulators collectively, and the Board has no guaranteed pharmacist, PPB or medication-safety expertise, despite making decisions affecting medicines, pharmacy premises, medication systems, facility accreditation and inspections.	Reject for reasons above
170		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah**	Amend paragraph (e) to read "three persons, not being a Governor, nominated by the Council of County Governors with knowledge in	To improve representation of county governments, under whose jurisdiction 99% of facilities operate, and to provide	Partly agree. A nominee of the council of county governors is already provided for. The committee also agrees that there is

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
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		Mercy et al.; Walter Lesaatin; Sheero M.	matters of health, quality management and quality improvement". Also Amend paragraph (f) to read "four persons appointed by the Cabinet Secretary, nominated by — (i) three health workers from the three most representative health professional associations; and (ii) one person from a patients' association in Kenya".	for equitable representation of health workers and providers.	need for inclusion of a person to represent the patients interests.
171		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend the Board composition clause to include additional members: (1) two persons nominated by a consortium of professional associations; (2) the Chief Executive Officers of all relevant regulatory bodies; and (3) one person nominated by the umbrella body of the most representative federation of trade unions — in addition to existing members.	Broad stakeholder inclusion ensures diverse professional perspectives, regulatory insights and worker interests are represented, enhancing decision-making, accountability and alignment with the Health Act and good governance practice.	Reject
172		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Amend clause 29 to include one member nominated by the union representing pharmaceutical technologists.	The Board relies on general administrative and political appointments and lacks representation for pharmaceutical technologists, who manage critical healthcare supply lines.	Reject
173		**Dr Joash Auka**	Amend clause 29(1) to include a	Health facility management,	Agree: this is already provided for

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			nominee of the Council of Governors, and insert a requirement for intergovernmental consultation before suspension, revocation or closure of a county-owned facility.	other than national referral facilities, is a devolved function under the Fourth Schedule. Article 6(2) requires consultation and cooperation between the two levels of government; a Board with no county voice risks unilateral national action against county facilities.	in the Bill
174		**Lab Medicine Society of Kenya (LMSK)**	Amend clause 29(1)(f) to read: "one person with knowledge in matters of medical laboratory diagnostics, nominated by the Kenya Medical Laboratory Technicians and Technologists Board". Further amend clause 29(1)(g) by inserting the words "registered and licensed by the relevant health professional regulatory body" after the word "providers". Insert a new clause 29(1A) as an anti-capture / cadre-diversity rule preventing both professional seats being filled with members registered under the same regulatory body.	The Board seat for expertise in "health, quality management and quality improvement" is nominated by the Council of County Governors, with no requirement of laboratory-specific competence and no role for KMLTTB. The "healthcare providers" seat carries no requirement of licensure. Nothing in the Bill prevents the Cabinet Secretary from filling both seats from the same profession, defeating the purpose of a dedicated diagnostics seat.	Reject
175		**George Okoth Osimbo**	Insert the words "and medical laboratory diagnostics and duly registered and licensed by the relevant Health Professional	Medical laboratory diagnostics underpin evidence-based diagnosis, disease surveillance and patient safety.	Reject

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			Regulatory Body" immediately after the words "quality improvemen" in the Council of Governors nominee paragraph.	Representation by a duly registered and licensed professional strengthens the Board's technical capacity.	
176		**Awuor Linet Owino; Levis O. Wandolo; Dr Royronald Ochieng Ongong'a**	Amend the Board composition clause to mandate that at least one seat be permanently held by a nominee of KMLTTB, and to require multi-disciplinary representation expressly naming Medical Laboratory Science alongside medicine, nursing, pharmacy and public health, with appointment on merit and quality-systems qualifications rather than cadre seniority.	Decisions on diagnostic quality, reagent standards and laboratory safety cannot safely be governed by a Board dominated by administrators, politicians and non-laboratory cadres lacking training in pathology and diagnostic technology. Diagnostic testing underpins over 70% of clinical decision-making. Exclusion offends Article 27(4) (equitable representation) and Article 232(1)(d).	Reject
177		**Kennedy Kinyua**	Add one nominee representing accredited health-training institutions and one additional patient/public-interest representative, with gender, disability and regional diversity requirements; require demonstrable patient-safety or quality-improvement expertise.	The Board has limited representation of patients, counties, frontline health workers, health professions and health-training institutions. A single nominee from "healthcare providers" cannot reflect the breadth of the sector.	Reject
178		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Amend clause 29(1)(g), by inserting the words after the words "through a transparent and competitive process prescribed in Regulations, from among nominees submitted by	No nominating body is identified and no nomination process prescribed, so the determination of which organisations nominate rests entirely on administrative	Reject

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			associations of health facilities registered in Kenya, having regard to the need for representation of health facilities across all levels of care" immediately after the words "nominated by healthcare providers"	discretion without published criteria.	
179		**Kenya Union of Clinical Officers (KUCO)**	Provide at least two county nominees with health/quality and county public-service experience; at least two nominees of statutory professional regulatory bodies on a rotational basis; and representation of healthcare-worker and professional organisations in addition to provider and consumer representation.	Articles 10, 174, the Fourth Schedule to the Constitution and the Intergovernmental Relations Act require inclusive representation and respect for devolution.	Reject: the Bill already provides for a nominee of the council of county governments who is not a Governor.
180		**Youth Champions for SDGs**	Reserve at least three seats on the Board for youth representatives nominated through a transparent, competitive process, and establish a Youth Advisory Panel to the Authority.	Young people constitute a significant portion of Kenya's population but the Bill does not ensure youth representation in the governance of the Authority.	Reject
181		**Francis Tauwo**	Increase representation of patient advocacy groups, persons with disabilities, women's organisations and marginalised communities, selected through a transparent process.	The Board composition appears to have limited patient and public representation.	Reject
182		**Rural & Urban Private Hospitals**	Amend First Schedule, paragraph 1(12) to read: "The quorum for the	The chairperson together with the four ex-officio State members	Accept: this is already provided for in the Bill

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		Association of Kenya (RUPHA)	meetings of the Board shall be five members, including at least two of the members appointed under section 29(1)(f), (g), (h) or (i)."	constitutes exactly five members. That group alone forms a quorum and carries any vote. A validly constituted meeting may therefore be held, and every decision of the Board taken — approval to construct or operate, registration, licensing, accreditation, the published quality score, performance ratings, appointment of inspectors and quality assessors, immediate suspension, closure and access to the Social Health Insurance Fund — without a single independent member present.	
183		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Insert a new clause 31(3): "A member appointed under section 29(1)(a), (f), (g), (h) or (i) may only be removed from office on the grounds specified in section 36(1), and the provisions of section 36(2) shall apply to any such removal."	The independent members have no security of tenure. Clause 36 protects the Chief Executive Officer by specifying eight grounds of removal and requiring compliance with Article 47 and the Fair Administrative Action Act. The salaried officer is protected; the members whose independence the Board's balance depends upon are not. Security of tenure is the substance of independence, and where the Act is silent the omission cannot be cured by Regulations.	Reject

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184	**Clause 30 – Qualifications of the Chairperson and Board members**	**Kenya Medical Association (KMA)**	Define "healthcare sciences" in clause 2, and require that any Board member or Chairperson who is a health professional be registered and in good standing with their regulatory body and, where applicable, their professional association.	An undefined qualification invites appointment of a Chair without genuine clinical grounding to head a clinical standards body.	Reject
185		**Dr Ghalib Moseti Abdillahi**	Amend clause 30(1)(b) to define "healthcare sciences" in clause 2 and to require that the chairperson be a healthcare professional registered and in good standing with a recognised statutory regulatory body.	"Healthcare sciences" is nowhere defined in clause 2, permitting the appointment of a person without clinical grounding to head a clinical standards body.	Reject
186		**Lab Medicine Society of Kenya (LMSK)**	Amend clause 30(1)(b) to read: "… holds a degree in a health-related field from a university recognised in Kenya …" with an express list of qualifying regulators.	The current qualification requires only a "health-related" degree and names no licensing regulator, which in practice is read narrowly to favour a single profession and leaves other cadres' eligibility to administrative interpretation.	Agree: this is already provide for in the Bill
187		**Kennedy Kinyua**	Clarify that "healthcare sciences" includes medicine, clinical medicine, nursing, pharmacy, public health and allied health sciences.	The required degree for Chairperson and CEO may otherwise be interpreted narrowly and exclude suitably qualified public-health, nursing, allied-health or quality-and-safety leaders.	Reject
188		**Fredrick Osewe**	Amend the qualification for the	Aligns the Bill with the Kenya	Agree: This is sufficiently provided

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			Chairperson of the Board and the Chief Executive Officer from "Must be a holder of a bachelor's degree in any health-related field" to "Must be a holder of a bachelor's degree or its equivalent in any health-related field."	National Qualifications Framework (KNQF) Act, 2014, under which qualifications evaluated as equivalent to a bachelor's degree at NQF Level 7 should receive equal recognition. Several Higher Diploma qualifications in health are advanced specialist programmes developing clinical, technical, managerial and leadership competencies comparable to bachelor's degrees; restricting eligibility to degree holders would exclude highly qualified and experienced professionals.	in the Bill
189	**Clauses 35–37 – Chief Executive Officer**	**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend the CEO qualification clause to read: "(c) is a registered member of the relevant health professional regulatory body in good standing, having obtained positive recommendations from the requisite regulatory body and the relevant professional association, and meets the requirements of Chapter Six of the Constitution."	Requiring positive recommendations from the relevant regulator and professional association aligns with Health Act CEO qualification principles and Chapter Six integrity requirements, ensuring the CEO is a registered, reputable professional and upholds public confidence.	Agree; This is sufficiently provided as the clause provides that he has to be a person of good standing with the relevant regulatory body
190		**Lab Medicine Society of Kenya (LMSK)**	Amend the provision to read: "is a registered and licensed member of a health professional	The current qualification requires only that the person be "a registered member of a health professional body", which does	Agree; This is sufficiently provided as the clause provides that he has to be a person of good standing with the relevant regulatory body

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			regulatory body established under any written law".	not confirm current licensure and is silent on which regulators qualify.	
191	**Clause 38 – Staff of the Authority**	**Victor Osoo**	If the Authority is formed, recruitment should be from the statutory regulatory bodies already in existence.	Employing new staff into the Authority increases the public wage bill, which is already exploding.	Reject
192	**Clause 42 – Approval to construct or operate a health facility**	**Kenya Medical Association (KMA)**	Require the Authority instead to publish facility standards to be met before accreditation is granted, in place of upfront construction and operational-plan approval, with an explicit transitional provision confirming existing facilities are not required to seek retroactive approval.	A standards-based gate achieves the same patient-safety assurance without raising the cost of market entry or leaving existing facilities' status unclear.	Agree: This will be sufficiently addressed through regulations.
193		**Dr Maria Ogaya Gerald**	Clarify the relationship between the Authority and existing approval mechanisms to avoid duplication while promoting an enabling environment for healthcare practice. On clause 42(6), provide reasonable exit provisions subject only to safeguarding continuity of patient care and proper transfer of records.	Construction and licensing already involve county governments, the National Construction Authority, public health authorities and professional regulators. Requiring the Authority's approval before construction creates an additional regulatory hurdle at the earliest stage of establishing a facility, making new facilities slower and more expensive to open. Individual practitioners wishing to establish their own practices are affected	Agree: This is adequately addressed in the Bill

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				more than large investors, who are better positioned to navigate lengthy approval processes; this could lead to fewer practitioner-owned facilities and greater concentration of healthcare ownership. Clause 42(6) may also unnecessarily restrict proprietors from voluntarily closing facilities or retiring where operations become unsustainable.	
194		**George Okoth Osimbo**	Insert the words "subject to compliance with the applicable written laws and in consultation with the relevant Health Professional Regulatory Bodies where specialised health services are proposed" immediately after the word "operation". On the subclause providing for standards-development, insert the words "in consultation with the Authority, County Governments and the relevant Health Professional Regulatory Bodies".	Construction and establishment of specialised facilities such as medical laboratories, radiology centres and dialysis units require technical approval under profession-specific statutes. Standards governing health facilities directly affect professional practice, patient safety and specialised service delivery.	Reject: The Bill clearly separates the mandate of health professional bodies from the health facility regulation which will be the mandate of the Authority established under this law.
195		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Require a joint licensing framework combining the Authority, relevant boards and county governments.	Clause 42 overlaps with county planning functions and professional board licensing mandates.	Reject: The Bill clearly separates the mandate of health professional bodies from the health facility regulation which will be the mandate of the Authority

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					established under this law.
196	**Part IV (cll. 42–64) – Approval, registration, licensing and accreditation generally**	**Kenya Medical Association (KMA)**	Legally separate licensing from accreditation; permit the Authority to recognise credible independent or international accreditation bodies (for example KENAS, COHSASA or SafeCare-model bodies already used in the Kenyan private sector) rather than solely Authority-appointed assessors; and introduce risk-based tiering in the clause 93 Regulations proportionate to facility scale and risk.	The Bill combines registration, licensing and accreditation in a single Authority-run regime, creating up to five sequential compliance and fee events for one underlying question — whether a facility is safe to operate. A one-size-fits-all, multi-gate compliance regime is administratively unworkable and disproportionately burdens small, doctor-run outpatient practices compared with tertiary hospitals.	Reject: KENAS mandate is specifically limited to the function of assessing and accrediting conformity assessment bodies (CABs) in Kenya. For instance, KENAS accredits international bodies such as the Joint Commission International Accreditation (JCI), Safe Care and the International Organization for Standardization (ISO) which operate under international standards, to ensure conformity with global benchmarks, but does not set or enforce standards for accreditation of institutions.
197		**Kennedy Kinyua**	Create a single-window application, common facility identifier, coordinated inspection and fee schedule. Require service standards for decisions and deemed acknowledgement where the Authority fails to respond (without deeming safety approval). Permit multi-year, risk-based licences for consistently compliant facilities, and reduced or waived fees for public, faith-based, teaching and low-volume rural facilities. Phase accreditation by facility level.	The Bill establishes several sequential approvals and fees alongside county construction/public-health approvals, professional facility licences, digital certification and SHA processes. Repeated inspections and annual licensing create delay, cost and opportunities for inconsistent decisions.	Accept: The concerns raised are best addressed through regulations

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198		**Dr Ghalib Moseti Abdillahi**	Provide for a single digital application portal, one coordinated inspection, a consolidated facility licence, a predictable published fee schedule, risk-based inspection intervals and statutory processing timelines; provide reduced fees for public, rural and not-for-profit facilities and recognition of approvals issued by other competent agencies; and provide that quality standards be applied progressively having regard to the category of facility and resources available, where management has taken reasonable mitigation measures.	A facility must obtain approval to construct or operate, registration, an annual licence, accreditation and a quality assessment, each attracting a prescribed fee, in addition to county and public health approvals. The cumulative burden falls hardest on small clinics, rural facilities, faith-based hospitals and county facilities — the very facilities whose closure would leave populations unserved.	Accept: The concerns raised are best addressed through regulations
199		**Pharmaceutical Society of Kenya (PSK)**	Insert a new provision: "A pharmacy premise registered and licensed under the Pharmacy and Poisons Act shall not require a duplicate operational registration or licence under this Part. The Authority shall recognise a valid licence issued by the Pharmacy and Poisons Board, without prejudice to accreditation and facility-wide quality obligations under this Act."	Because pharmacies fall within the facility framework, PPB-licensed pharmacies may be required to obtain a second approval, registration, inspection and annual operating licence. Recognising PPB licences avoids conflicting licences, duplicate fees and inspections, uncertainty over final authority and unnecessary barriers to access.	Agree however the transitional provision sufficiently addresses the concerns of the stakeholder.
200		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah**	Retitle Part IV as "PART IV — ACCREDITATION OF HEALTH FACILITIES" and delete clauses 44–57 and 72 of the Act.	To align Part IV with the Authority's proper mandate as an accreditation and oversight body under a two-tier quality	Reject

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		Mercy et al.; Walter Lesaatin; Sheero M.		assurance framework.	
201		**Kenya Union of Clinical Officers (KUCO)**	Retitle and restructure Part IV around "Accreditation and Quality Rating of Health Facilities". Preserve statutory professional/premises licensing and county approvals. The Authority should maintain a quality-accreditation register integrated with the Digital Health Agency.	Avoids multiple licences, fees and inspections and prevents a central Authority from displacing specialised and devolved functions.	Reject
202		**Awuor Linet Owino**	Amend clause 27 to state that any facility already licensed and accredited by a specialised statutory board (such as KMLTTB under Cap. 253A) is deemed automatically compliant, removing the requirement for double-licensing and double-taxation.	Forcing laboratories to undergo dual registration and pay double licensing fees to both KMLTTB and the new Authority will financially cripple private diagnostic laboratories, lead to laboratory closures and restrict access to vital diagnostic testing.	Agree however the transitional provision sufficiently addresses the concerns of the stakeholder.
203		**Victor Osoo**	Delete Part IV (Registration, Licensure and Accreditation) completely.	It will interfere with the work of other regulators who register and license facilities.	Reject
204		**Dr Maria Ogaya Gerald**	Delineate responsibilities between the Authority and existing councils, limiting the Authority to system-level quality oversight; harmonise responsibilities and avoid parallel accreditation or compliance systems.	Many responsibilities in clauses 43–58, 70 and 73 are similar to functions already undertaken by KMPDC and other statutory regulators, which may result in duplicated inspections, inconsistent directives and increased administrative burden,	Agree, however the Bill sufficiently separates the regulation of health professionals from the regulation of health facilities which will be the domain of the Authority established under this law.

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				and parallel processes may create conflicting standards.	
205	**Clauses 43–47 – Registration and certificate of registration**	**George Okoth Osimbo**	Insert into the pre-registration inspection clause the words "jointly with the relevant Health Professional Regulatory Body where the inspection relates to specialised professional services". Insert a new subsection requiring that before refusing registration the Authority shall accord the applicant an opportunity to be heard and communicate the deficiencies requiring rectification.	Professional regulatory bodies possess the statutory mandate and technical expertise to inspect specialised services including medical laboratories. Refusal to register constitutes administrative action affecting constitutional rights, so an express right to be heard strengthens compliance with Article 47 and the Fair Administrative Action Act, 2015.	Reject: the Bill sufficiently separates the regulation of health professionals from the regulation of health facilities which will be the domain of the Authority established under this law.
206		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend clause 46(1)(b)(ii) to read: "(b)(ii) demonstrate that the facility has, or will have upon opening, healthcare provider staffing levels in accordance with the Ministry of Health Human Resources for Health Norms and Standards Guidelines approved by the Cabinet Secretary, showing compliance with prescribed provider-to-patient ratios required for the services to be offered."	Ensuring that facilities demonstrate adherence to MOH HRH Norms and Standards guarantees adequate staffing, which is essential for safe, quality service delivery and accreditation compliance.	Reject
207		**Pharmaceutical Society of Kenya (PSK)**	Replace clause 44(1)(d) with: "Evidence that the facility will	The clause may permit any registered healthcare professional to be treated as technically	Reject

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			operate under the technical direction of a healthcare professional whose qualifications and lawful scope are appropriate to the facility's principal services; provided that a pharmacy premise shall remain under the professional control prescribed under the Pharmacy and Poisons Act."	qualified to manage any type of facility, including a pharmacy. The amendment preserves inclusive health-facility leadership while ensuring profession-specific services remain under appropriately qualified technical control.	
208		**Kinyua Murithi**	Correct the apparent missing apostrophe in "facility's" at clause 44(1)(b).	The sentence is semantically incorrect as drafted.	Agree
209		**Collins Omollo**	In clause 46(3), delete the words "twenty-one days" and replace with "thirty days". In clause 47(3), delete the words "twenty-one days" and replace with "thirty days".	To regularise clauses 46(3) and 47(3) so that they match the timelines set in clause 95.	Reject
210	**Clauses 46, 48, 54–55 – Suspension and revocation of registration or licence**	**Kenya Medical Association (KMA)**	Require suspension to be preceded by written notice of non-compliance and a reasonable opportunity to remedy, reserved for non-compliance found not to be a minor or technical breach capable of correction.	The Authority may suspend a certificate of registration or licence on broad grounds, including any failure to comply with the Act, without an express requirement of proportionality. A graduated compliance ladder protects continuity of patient care and is consistent with fair administrative action under Article 47.	Agree. This is sufficiently addressed in the Bill.
211		**George Okoth Osimbo**	Substitute the suspension ground with:	The existing provision is overly broad and may permit suspension for minor administrative	Reject

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			"the holder materially fails to comply with the provisions of this Act after being issued with a notice to remedy the non-compliance within the prescribed period."	infractions. The amendment introduces proportionality and procedural fairness consistent with Articles 47 and 50.	
212		**Collins Omollo**	Add a new clause 55(4A) immediately after clause 55(4): "(4a) A person aggrieved by the decision of the Authority under this section may within 30 days from the day of the notification of the revocation lodge an appeal before the Tribunal."	To provide for a right of appeal to the Tribunal against revocation of a licence by the Authority.	Agree however the Bill provides for a right of review as well as referral for any dispute under this Act to the Healthcare Tribunal. The concerns of the stakeholder are therefore sufficiently addressed.
213		**Dr Joash Auka**	Lengthen the response and appeal windows for facility enforcement under clauses 46(2), 54(2) and 63(2) to no less than twenty-one and thirty days respectively, or expressly extend the Fair Administrative Action Act's proportionality standard to Part V.	A facility facing suspension or revocation is given only fourteen days to respond and twenty-one days to appeal, for sanctions that may include closure and fines of up to twenty million shillings — a materially shorter and less protective process than the Bill affords its own Chief Executive Officer facing removal under clause 36(2), which expressly invokes the principles of fair administrative action. The Bill should not apply a lower due-process standard to facility closure than to the internal removal of its own officer.	Reject

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214	**Clauses 56–64 – Accreditation of health facilities**	**Millicent Olulo (PharmAccess)**	Assign the accreditation function to an independent accreditation body distinct from the Authority's regulatory and licensing functions; and develop a framework for recognition and reciprocation of existing certification/accreditation schemes aligned to the Kenya Quality Model for Health (KQMH).	International best practice separates accreditation and certification from registration and licensing to ensure independent, unbiased assessment and avoid a conflict of interest. Mutual recognition streamlines accreditation, reduces regulatory burden and enables recognition by international insurers in addition to SHA.	Reject
215		**Council of Governors (CoG)**	Insert a new section entitled "Recognition of Existing Accreditation Programmes": "(1) The Authority may recognize, designate or enter into mutual recognition arrangements with accreditation programmes or accrediting bodies that meet standards prescribed under this Act. (2) Accreditation by a recognized accrediting body may be accepted as satisfying equivalent requirements under this Act. (3) The Authority shall establish a framework for harmonization, mutual recognition and transition of existing accreditation programmes into the national accreditation system."	This preserves investments already made by health facilities, avoids duplication and encourages harmonisation rather than replacement of existing quality programmes.	Reject

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216		**Kinyua Murithi**	Add a new subsection to clause 57(4): "The Authority may issue frameworks for recognition of accreditations issued by other recognized national or international accreditation bodies."	There exist accepted national and international accreditation bodies for healthcare facilities such as NQI/KEBS, JCI and SafeCare.	Reject: The enforcement of health standards in Kenya is a function of the ministry of health.
217		**Tom Kauki**	Revise clause 58(1) to read: "A person may apply to the Authority for accreditation of a health facility under this Act." Revise clause 62 to read: "A health facility may, ninety days prior to the expiry of the accreditation make an application for renewal of the accreditation of the health facility."	Page 4 of the Bill Digest, under the header "Registration, Licensing and Accreditation of Health Facilities", provides that a facility may seek accreditation for quality of healthcare. The intent is to make accreditation non-compulsory; lack of accreditation is not an offence, so "shall" should become "may".	Reject
218		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Insert a new clause 57(4): "Sections 72, 75 and 77 shall apply, with the necessary modifications, to quality assessors appointed under subsection (2)(b)." Also consider adding a provision that "No accreditation assessment shall	Clause 57(2)(b), inserted at Third Reading, creates the office of quality assessor but makes no provision for appointment, qualifications, conduct, reporting obligations, or objection to findings. Inspectors, by contrast, are appointed by Gazette notice, must hold prescribed qualifications, are subject to a	Reject

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			be conducted under this Act before the code of conduct required under section 77 has been prescribed and published."	mandatory code of conduct, must prepare a report identifying the evidentiary basis of enforcement action, and are subject to facility objection. The function with the greater financial consequence is the less regulated.	
219		**George Okoth Osimbo**	Insert the words "without prejudice to the statutory accreditation functions of Health Professional Regulatory Bodies under any written law" immediately after the words "health facilities" in clause 56. In clause 57(1), insert the words "Developed in consultation with the relevant Health Professional Regulatory Bodies" after the words "quality healthcare standards". Substitute clause 59(d) with: "conformity with disease-specific clinical guidelines and profession-specific practice standards developed or approved by the relevant Health Professional Regulatory Bodies."	Several regulatory bodies, including KMLTTB, have statutory powers to approve, inspect and accredit specialised facilities for professional practice and training. Clinical guidelines alone are insufficient to assess compliance in specialised professional practice.	Reject: The Bill clearly separates health professionals regulation from health facilities regulation.
220		**Kenya Medical**	On clause 65(4), insert a minimum	SHIF empanelment and	Reject

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		Association (KMA)	twenty-four-month phased implementation period, with Authority-facilitated technical and financial support, before SHIF empanelment may be withdrawn for non-accreditation; and provide that compliance with the quality-improvement framework inform, rather than solely determine, SHIF accreditation eligibility.	continued contracting are tied directly and immediately to accreditation status. Immediate loss of SHIF revenue risks abrupt harm to small and rural facilities, undermining equitable access to care.	
221	**Clauses 66–67 – Quality assessment, scoring, rating and publication**	**Dr Geoffrey K. Maiyoh**	Amend clause 66(4) by inserting the words "and shall also publish the results of the quality assessment and quality rating on a publicly accessible website or mobile platform, updated at least quarterly, in a format understandable to the general public." Immediately after the word "Gazette":	The Gazette is not easily accessible to ordinary citizens and is published infrequently. Swiss law mandates that all hospitals publicly report their infection rates, surgical revision rates and patient satisfaction scores on public dashboards, empowering patients to choose safer facilities and driving competition on quality.	Agree
222		**Kenya Medical Association (KMA)**	Require written notice and a defined period (recommended thirty days) to respond or take corrective action before an adverse rating or non-compliance notice is gazetted or published, with the facility's current rating preserved pending any Tribunal appeal.	Publication of adverse quality ratings or non-compliance notices is not preceded by a defined notice-and-response period, exposing facilities to reputational harm based on findings they have not had a fair opportunity to contest or correct.	Agree however the concerns of the stakeholder can be effectively addressed through regulations
223		**Pharmaceutical Society of Kenya**	Provide that an adverse rating shall not be published until the period for	Balances transparency and patient protection with fair	Reject for reasons provided above

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		(PSK)	internal review or appeal has expired or the review or appeal has been determined, except where immediate disclosure is reasonably necessary to protect the public from a documented safety risk.	administrative action. Legal basis: Constitution Article 47; Fair Administrative Action Act.	
224		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Add a proviso to clause 66(4) deferring publication of results until any review or appeal has been determined.	Publication of an adverse rating before an appeal is determined causes reputational and financial loss that a subsequent correction cannot repair.	Reject for reasons provided above
225		**George Okoth Osimbo**	Insert the words "after communicating the results to the affected health facility and determining any review or objection lodged by the facility" immediately before the words "publish in the Gazette".	Publication of quality ratings may have significant reputational and commercial consequences. The amendment guarantees procedural fairness and the right to administrative review before publication, consistent with Articles 46, 47 and 50.	Reject for reasons provided above
226		**Kennedy Kinyua**	Require transparent indicators, case-mix and resource-level adjustment, independent validation, a pre-publication correction period, plain-language explanations and separate reporting of structural constraints. Prohibit league tables based on unvalidated or statistically unstable data.	Publishing raw scores without risk adjustment can unfairly penalise referral and teaching hospitals that manage more complex patients. Data errors may cause reputational and financial harm, and the Bill does not require validation, contextual notes, correction rights or publication of methodology.	This is noted, however, the same can be effectively addressed through regulation.
227		**IDinsight Dignity Initiative**	Insert a new subsection in clause 66 to provide:	Published quality ratings should reflect patients' own experience	This is noted, however, the same can be effectively addressed

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			"The quality scoring and rating framework shall include a domain on patient satisfaction as defined in section 2."	of dignity and respectful care, disaggregated by county and by sex, age, disability and socio-economic status.	through regulation.
228	**Clause 68 – Enforcement measures of the Authority**	**Kenya Medical Association (KMA)**	Define "immediate risk" in clause 2; require independent review of any closure order within seventy-two hours; require an inspector's immediate suspension order to be countersigned by the Chief Executive Officer or a designated senior officer within twenty-four hours to remain in force; and, short of imminent risk, provide a defined right to be heard (recommended fourteen days) before other adverse enforcement action, supported by a designated quality-assurance review panel with professional-council and private-sector representation.	Facility closure has severe consequences for patient continuity of care and practitioner livelihoods; the current formulation is too open-textured and lacks a fast-track safeguard against error or misuse.	Reject
229		**George Okoth Osimbo**	Delete clause 68(c) (imposing fines or penalties). Substitute clause 68(e) with: "recommending closure of a health facility where non-compliance poses an immediate and demonstrable risk to patient safety or public health, after consultation with the relevant Health	The Bill does not prescribe the nature, limits or procedure for administrative penalties; granting the Authority unrestricted power to impose fines contravenes the principles of legality, proportionality and fair administrative action under Articles 47 and 50. Closure is among the most severe administrative sanctions and	This is noted. The concerns of the stakeholder can be effectively addressed through regulations.

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			Professional Regulatory Body and in accordance with Article 47 of the Constitution, except where immediate emergency action is necessary to avert imminent danger."	directly affects rights under Articles 40, 43, 47 and 50.	
230		**Dr Ghalib Moseti Abdillahi**	Amend clauses 79 and 80 to require, before any closure or suspension takes effect: written reasons and objective evidence of immediate and serious risk; approval or prompt review by a senior officer of the Authority; notification of the relevant county government; a patient transfer and continuity-of-care plan; preservation of emergency and maternity services where this can be done safely; and an expedited hearing and right of appeal.	The power is necessary but the safeguards are thin. There is no requirement that a patient transfer plan exist before closure, no requirement to notify the county government responsible for service delivery, and no expedited hearing. Sudden closure of a maternity unit, dialysis centre, ICU or ambulance service can itself endanger patients — in maternal health the risk falls on patients already in labour.	Reject
231	**Clause 70 – Public register of health facilities**	**Dr Joash Auka**	Amend clause 70 to provide that the Authority's register shall be drawn from, and remain synchronised with, the Comprehensive Integrated Health Information System facility registry as the single source of truth.	The Bill establishes a second, independently maintained register, duplicating the facility registry the Digital Health Agency already maintains under the Digital Health Act, 2023. Two statutory bodies maintaining parallel registries of the same facilities, with no reconciliation clause, will generate conflicting records and duplicate compliance burdens.	Reject

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232		**IDinsight Dignity Initiative**	Require publication in the public register of patient satisfaction data disaggregated by county and by sex, age, disability and socio-economic status for the groups protected by clause 15(2)(c).	Disaggregated publication makes the equity commitment in the Bill measurable and allows each senator to read the result for their own county each quarter.	Reject
233	**Clauses 72–77 – Inspectors, qualifications and conduct**	**Kenya Medical Association (KMA)**	Require that inspection of clinical services, and the newly created quality-assessor function, be conducted by, or in the presence of, a healthcare professional registered with the relevant professional council, with minimum professional qualifications and conflict-of-interest disclosure specified for both roles.	A person inspecting, assessing or certifying clinical services must be able to interpret clinical practice; an administratively qualified inspector or assessor alone cannot reliably perform this function.	Reject: The Bill clearly separates the regulation of health professionals from the regulation of health facilities.
234		**Dr Ghalib Moseti Abdillahi**	Amend clause 72(1) to provide that inspection of clinical services be conducted by, or in the presence of, a healthcare professional registered and in good standing with the relevant statutory regulatory body, and that the qualifications of inspectors be prescribed in Regulations rather than by the Authority. Insert in clause 76 a new subsection: "An inspector may document and refer suspected professional incompetence, misconduct or	Read together, clauses 72(1), 73(2)(b), 74(e), 75 and 79(1)(a) allow a person with no clinical qualification, appointed on criteria the Authority sets for itself, to assess the professional competence of a specialist practitioner and to suspend the service that practitioner provides. Nothing requires an inspector examining an obstetric theatre, a neonatal unit or an intensive care unit to hold any clinical qualification, and no provision protects a practitioner from parallel jeopardy before the	Reject: The Bill clearly separates the regulation of health professionals from the regulation of health facilities.

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			practice outside an authorised scope to the relevant statutory professional regulatory body, but shall not make a final determination on the professional liability or fitness to practise of an individual healthcare professional."	employer, the Authority, the council and the Tribunal for the same conduct.	
235		**George Okoth Osimbo**	In clause 72(1), insert the words "in consultation with the relevant Health Professional Regulatory Bodies and the Public Service Commission" immediately after the words "appoint health facility inspectors". Delete clause 73(2)(b). Insert a new paragraph in clause 74 to provide: "(i) where an inspection concern specialised professional services, undertake the inspection jointly with the relevant Health Professional Regulatory Body." In clause 76(1)(b)(ii), insert the words "after consultation with the relevant Health Professional Regulatory Body where the findings relate to specialised professional services".	The Authority should not unilaterally determine the qualifications of inspectors assessing specialised services. Determination of professional competence is the exclusive statutory mandate of the professional regulatory bodies through registration, licensing, CPD and disciplinary processes; retaining clause 73(2)(b) creates duplication and may result in conflicting determinations.	Reject: The Bill clearly separates the regulation of health professionals from the regulation of health facilities.

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236		**Pharmaceutical Society of Kenya (PSK)**	Insert a provision requiring that an inspection concerning pharmacy premises, dispensing, medicines storage, controlled medicines, pharmacovigilance, pharmaceutical waste or the pharmaceutical supply chain be conducted jointly with the Pharmacy and Poisons Board or by a PPB-authorised inspector, and that the inspection team include a registered pharmacist.	General facility inspections may not adequately assess lawful pharmacy supervision, medicine storage, dispensing systems, controlled medicines and pharmacovigilance. Joint inspection preserves specialist competence and avoids duplication.	Reject: The Bill clearly separates the regulation of health professionals from the regulation of health facilities.
237		**Lab Medicine Society of Kenya (LMSK)**	Insert into clauses 72 and 74 a provision to the effect that: "Where an inspection concerns laboratory services, the inspection team shall include a qualified medical laboratory professional nominated by the Kenya Medical Laboratory Technicians and Technologists Board."	There is no requirement that inspectors assessing laboratory services hold laboratory expertise, or that a qualified laboratory professional sit on any team inspecting a medical laboratory.	Reject: The Bill clearly separates the regulation of health professionals from the regulation of health facilities.
238		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend Part V to establish an Inspectorate Unit rather than individual inspectors: the Unit shall comprise qualified inspectors seconded from relevant regulatory bodies working collaboratively under the Director-General; all inspection, investigation and enforcement activities shall be conducted by the Unit; and Regulations shall detail	Vesting inspection powers in individual inspectors' risks bias, corruption or unlawful discretion targeting facilities or providers. A collective Inspectorate Unit promotes collective decision-making, reduces individual bias, enhances transparency and leverages multi-disciplinary expertise.	Reject

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			composition, rotation and conflict-of-interest measures.		
239		**Kennedy Kinyua**	Set minimum inspector qualifications in the Act; use multidisciplinary inspection teams; require official identification and written scope; obtain a warrant for non-consensual searches unless an imminent risk exists; minimise access to identifiable clinical records; document samples and evidence; and require review of an emergency suspension by the Authority within 48 hours. Give facilities reasons, evidence, a hearing and an appeal without compromising urgent patient protection.	Inspectors receive extensive entry, search, sampling, interview and seizure-related powers, with qualifications left to the Authority and no clear rules on identification, warrants, patient privacy, privileged records, conflicts of interest, chain of custody, proportionality or rapid review of emergency closure orders.	This is noted, however, this will best be addressed through regulations as provided for under clause 70 (1).
240		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Amend clause 74 to mandate inspectors to use a transparent checklist aligned with existing professional board metrics.	The clause grants broad powers to enter premises, seize materials and audit records but lacks a standardised, objective inspection protocol, leaving room for arbitrary enforcement actions.	Reject
241		**Dr Geoffrey K. Maiyoh**	Amend clause 73(1) by inserting after the words "announced and unannounced": "provided that the Authority shall ensure that at least 50% of all routine inspections are unannounced and conducted without prior notice to the health	The clause does not mandate a minimum proportion of unannounced visits, allowing facilities to prepare for inspections and conceal systemic failures. The Dutch Health and Youth Care Inspectorate	Reject

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			facility."	conducts random unannounced spot-checks and Japan uses unannounced "secret shopper" patient-safety audits; this detects real-time failures and builds public trust.	
242		**Tom Kauki**	Revise clause 73(1) to read: "The Authority shall establish a planned and systematic inspection programme consisting of pre-registration, pre-licensure, routine and reactive inspections that are announced or unannounced to monitor compliance with —"	As drafted, the section does not provide for pre-registration and pre-licensure inspections.	Reject
243		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Amend clause 73(1)(b) (cited as 75(1)(b)) by deleting the words "registration", "licensing" and "and" to read" "(b) the terms and conditions of accreditation issued by the Authority." Amend clause 74(a) (cited as 76(a)) by deleting the words "registration" and "licensing", to read "(a) inspect a health facility for purposes of accreditation".	To align the inspection and enforcement provisions with the Authority's proper mandate as an accreditation and oversight body.	Reject

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			Amend clause 76(b)(ii) (cited as 78(b)(ii)) to read "suspending accreditation due to non-compliance with the quality of healthcare standards set by the Authority".		
244		**David Wekesa**	Retain Authority facility inspection, but require coordination with KMLTTB whenever the inspection concerns medical laboratory professional practice or laboratory-specific technical requirements.	Section 60 of the Health Act states that respective regulatory bodies inspect, monitor and evaluate the services and professionals they regulate, and KHPOA coordinates joint inspections. A broad Authority inspection power may duplicate professional regulatory inspections, producing multiple inspections, contradictory corrective actions and unclear enforcement authority.	Reject: The Bill clearly separates the regulation of health facilities from health professionals.
245	**Clauses 79–80 – Immediate suspension and enforcement pending review**	**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	In clause 79(5) substitute the word "shall" for "may". Add a proviso to clause 94(3) to provide: "provided that an application for review of a decision to suspend or revoke a certificate of registration, a licence or an accreditation shall operate as a stay of that decision, unless the Authority certifies in writing that the continued operation of the health facility poses an	A facility may be closed by a single officer, the safeguard against that closure need never be brought into existence, and an application for review does not halt the closure while it is determined. Clause 94(2) allows the Authority sixty days to determine a review, and an appeal lies to a Tribunal that must first be constituted. For a Level 2 or Level 3 facility, a suspension of several weeks is not a reviewable inconvenience;	Agree: The concerns of the stakeholder are already addressed in the Bill

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			immediate risk to patient safety."	it ends the facility and removes the only available service from that catchment.	
246		**George Okoth Osimbo**	Substitute clause 79(1)(a) with: "Recommend to the Authority the temporary suspension of a healthcare service or health facility, except where there exists an immediate and demonstrable threat to life or public health requiring urgent intervention." Delete clause 80(1)(e). In clause 80(3), insert the words "after giving the affected person an opportunity to be heard, except where immediate action is necessary to prevent imminent danger to life or public health".	The power to summarily suspend operations affects constitutional rights under Articles 40, 43, 47 and 50 and should ordinarily vest in the Authority following due process. The Board cannot create penalties through administrative action — the creation of offences and penalties is a legislative function reserved to Parliament under Article 94.	Reject
247		**Kenya National Union of Pharmaceutical Technologists (KNUPT)**	Mandate the written concurrence of the County Director of Health prior to closing public healthcare facilities.	Clause 79 allows unilateral closure of public facilities, risking sudden disruptions to local emergency care networks.	Reject
248	**Clause 82 – Inspection of records**	**Dr Ghalib Moseti Abdillahi**	Amend clauses 82 and 96 to require compliance with the Data Protection Act; limit access to the minimum identifiable information necessary for a lawful inspection; require de-	Medical records contain sensitive personal data protected under Article 31 of the Constitution and the Data Protection Act. The Bill provides no penalty for	Agree

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			identification of information used for quality analysis, rating or publication; prescribe secure storage, transmission and retention periods; and create an offence of unauthorised disclosure by an employee, agent or inspector of the Authority.	unauthorised disclosure by an inspector or officer of the Authority.	
249		**Kinyua Murithi**	Delete clause 49(f) (demand for data on non-healthcare professional employees).	The demand for data on non-healthcare professional employees, including watchmen and orderlies, is strenuous (numbers are affected by high attrition), unnecessary and intrusive, and offends data-minimisation principles as the Authority has not been obligated to process that data.	Reject
250		**Lydia Nyawira Mburia**	Under Part V (clauses 81–82), develop a harmonised, customer-centric Healthcare Records Management Information System; require periodic health-records and ICT audits; create tamper-proof ICT records systems ensuring security, confidentiality and safe custody in compliance with the Access to Information Act (Cap. 7M), the Data Protection Act No. 24 of 2019 and Article 35 of the Constitution; establish decision-support and county-level executive information	A harmonised, user-friendly records management system would bridge technology and operations, deliver organised and actionable reports the public can use to evaluate performance, protect records against cybersecurity and information security threats, reduce bureaucracy and enhance transparency and access to information.	

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)					
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			systems with public dashboards; and allocate adequate funds through the ICT Authority and Ministry of Health for implementation.		
251	**Clause 83 – Establishment and composition of the Health Care Tribunal**	**Kenya Medical Association (KMA)**	Allocate the four professional Tribunal seats across named disciplines (medicine and dentistry, nursing, pharmacy, and allied health), supplemented by a standing technical assessor for other technical areas such as digital-health disputes. Raise the quorum under clause 83(4) to five members, with a provision that no meeting shall be properly constituted for the hearing or determination of any matter unless at least two of the members present are members appointed under clause 83(2)(c).	The four professional seats are not allocated across specific disciplines despite a docket spanning medicine and dentistry, nursing, pharmacy and allied professions. A quorum of three out of eleven members is low and, as drafted, can lawfully be constituted entirely from the Chairperson, the three advocates or the three non-clinical "other persons", excluding every clinical member.	**Accept:** There are four seats reserved to the Tribunal for healthcare professionals under clause 83 (1) (c). This is already addressed by the Bill.
252		**Confraternity of Patients Kenya (COFPAK)**	Add a paragraph to clause 83(4) to provide: "(d) one member representing patient interests, with demonstrable experience in Quality Improvement and patient safety advocacy"	A patient representative on the Tribunal ensures that the perspectives, rights and interests of patients are adequately represented, promoting patient-centred decision-making, strengthening public confidence and enhancing accountability. This fosters a culture of trust, openness and respect, key to voluntary incident reporting and learning (Strategic Objectives 2 and 7 of the WHO Global Patient	**Agree.**

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				Safety Action Plan).	
253		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Amend clause 83(4) "cited as 85(4)" to read: "The Tribunal shall consist of members appointed by the Cabinet Secretary as follows — (a) a Chairperson who shall be a person qualified to be a judge of the High Court nominated by the Judicial Service Commission; (b) one advocate of the High Court of not less than five years' standing nominated by the Law Society of Kenya; (c) three health workers who shall possess knowledge and experience in matters of insurance, policy and quality improvement …" and add "(d) Chairpersons of regulatory bodies in the health sector".	To retain authority on management of health with the Cabinet Secretary for Health, to enhance representation of health workers and providers, and to ensure objectivity in decision-making.	**Reject:** under Article 169 (1) of the Constitution, all tribunals are categorized as subordinate courts and therefor under the control of the judiciary and not the ministries.
254		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Amend Part VI to specify that Tribunal membership shall include one representative nominated by each relevant regulatory body responsible for health professions; and require the Cabinet Secretary to make rules for operationalising the Tribunal in consultation with all	Including representatives from all relevant regulatory bodies ensures Tribunal decisions benefit from sector-specific expertise, upholds fairness and transparency, and aligns with principles of inclusive governance.	**Accept:** There are four seats reserved to the Tribunal for healthcare professionals under clause 83 (1) (c). This is already addressed by the Bill.

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			respective regulatory bodies.		
255		**Pharmacare MTM Solutions**	Ensure that the composition of both the Authority's Board and the Health Care Tribunal includes a member with pharmaceutical or medicines-safety expertise, alongside the medical, nursing and legal expertise already contemplated.	A material share of quality-of-care disputes involve medicines-related harm; adjudication must be properly informed on medicines-related matters.	**Accept:** There are four seats reserved to the Tribunal for healthcare professionals under clause 83 (1) (c). This is already addressed by the Bill.
256		**Dr Royronald Ochieng Ongong'a**	Require that the Tribunal include, on a rotating or matter-specific basis, an assessor or member drawn from the medical laboratory profession (nominated by KMLTTB) whenever a matter directly concerns diagnostic or laboratory practice.	The Tribunal's composition risks being dominated by a single professional perspective, undermining fairness and diagnostic-specific competence, contrary to Articles 27 and 50 of the Constitution.	Reject
257		**George Okoth Osimbo**	Substitute clause 83(4)(c) by inserting the words "including at least three persons nominated from Health Professional Regulatory Bodies established under written law" immediately after the words "quality improvement".	The Tribunal will determine disputes affecting regulated health professions. Inclusion of persons with regulatory expertise enhances technical competence, promotes informed adjudication and strengthens confidence in the Tribunal's decisions.	
258		**Kennedy Kinyua**	Require each merits panel to include legal, clinical/quality and public-interest expertise; provide interim relief, remote filing, regional accessibility and cost-proportionate procedures.	A quorum of three could determine complex matters without clinical expertise.	**Reject**

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259	**Clause 84 – Jurisdiction of the Tribunal**	**Kenya Medical Association (KMA)**	Amend clause 84(4) to read: "The Tribunal shall have appellate jurisdiction over the decisions of the Authority made under this Act", deleting the reference to "any relevant regulatory body", so that appeals against professional regulatory body decisions continue on their existing statutory track (for example to the High Court under the Medical Practitioners and Dentists Act).	The Tribunal, as constituted under clause 83, has only four of eleven members drawn from the healthcare professions; extending its jurisdiction to professional disciplinary appeals risks decisions on complex clinical and ethical matters being made by a majority lay/legal panel, displacing established peer-review safeguards.	**Accept:** Reference to the term "any relevant regulatory body" could extent the jurisdiction of the Tribunal beyond the role of the Quality Healthcare and Patient safety Authority.
260		**Dr Ghalib Moseti Abdillahi**	Delete the words "and any relevant regulatory body in the health sector" from clause 84(4), so that it reads: "(4) The Tribunal shall have appellate jurisdiction over the decisions of the Authority made under this Act relating to health facilities, registration, licensing, accreditation, inspection and institutional quality, and may refer any matter back to the Authority for re-consideration." Insert a saving provision preserving appeals under the professional Acts.	This subordinates the licensing and disciplinary determinations of independent statutory councils to a body on which they have no representation. It also duplicates appeal mechanisms the Bill itself preserves elsewhere — items 11 to 13 of the Second Schedule retain High Court appeals under the Pharmacy and Poisons Act — producing two inconsistent appellate pathways from the same decision with no provision governing which prevails.	**Agree** for reasons given above
261		**George Okoth Osimbo**	In clause 84(1), substitute the words "or any other Act" with "where	As drafted, the Tribunal assumes unlimited jurisdiction over	**Accept**: The concerns are already addressed in the Bill.

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			jurisdiction is expressly conferred by that written law". In clause 84(3), insert the words "arising under this Act" after the words "any dispute". In clause 84(4), delete the words "and any relevant regulatory body in the health sector". In clause 84(5), delete the word "penalties".	disputes arising under any health legislation, potentially overriding specialised tribunals and statutory appeal mechanisms. It effectively makes the Tribunal the appellate body for all Health Professional Regulatory Bodies despite the appeal mechanisms in their respective Acts, amending those statutes by implication. Tribunals adjudicate disputes but do not impose punitive sanctions unless expressly authorised.	
262		**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Restore clauses 84(1) and 84(3) as they appeared in the Bill as introduced: clause 84(1) — "…relating to the health sector arising under this Act or any other written law"; clause 84(3) — "…any dispute between health facilities, patients, healthcare providers and regulatory bodies." In the alternative, support a time-limited provision conferring succession to the Dispute Resolution Tribunal under section 44 of the Social Health Insurance Act until that Tribunal is constituted.	Facilities have no functioning forum for disputes concerning empanelment, contracting, claims and termination. The Dispute Resolution Tribunal under section 44 of the Social Health Insurance Act, 2023 has not been constituted, although its Tribunal Procedure Rules were gazetted on 8 March 2024 and the Social Health Insurance Regulations direct a provider aggrieved by termination of contract to appeal to it. The consequence is that decisions extinguishing a facility's revenue remain, in practice, unappealable.	**Reject**

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263		**Kennedy Kinyua**	Limit the Tribunal to disputes and appeals arising from decisions under this Act; preserve jurisdiction expressly assigned elsewhere; harmonise appeal periods and clarify whether internal review is optional and how it affects time.	The Tribunal's original jurisdiction over any facility–patient dispute and appellate jurisdiction over any relevant professional regulatory body is very broad and may conflict with specialised statutory tribunals and ordinary courts.	Agree
264		**Kenya Union of Clinical Officers (KUCO)**	Support an independent Tribunal for decisions under this Act, but amend clause 84(4) so that it does not automatically displace specialist appeal routes created by other Acts; its jurisdiction over professional regulators should be limited to matters expressly conferred by Parliament or cross-regulatory disputes under this Act.	Profession-specific disciplinary and appeal mechanisms already exist and should not be displaced by implication.	Agree
265		**David Wekesa; Daniel Kitunga**	Delete any provision conferring original jurisdiction on the Tribunal over professional disciplinary proceedings; limit it to quality and patient-safety disputes and appeals expressly provided by law. Clarify that the Tribunal shall not exercise disciplinary jurisdiction over matters expressly reserved for professional regulatory bodies, and that appeals from professional disciplinary proceedings continue to follow the procedures under the	KMLTTB has an established professional disciplinary framework. Dual accountability — KMLTTB disciplinary proceedings plus Tribunal proceedings for the same professional conduct — creates the risk of conflicting decisions and double jeopardy.	Agree

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			respective professional Acts.		
266		**Rewam Consultancy**	Define the Tribunal's scope to handle only disputes related to quality of care and patient safety, while referring professional misconduct cases to the relevant professional councils; establish formal referral protocols between the Tribunal and existing regulatory bodies.	The Tribunal's mandate is broadly defined, which may lead to jurisdictional overlaps with existing bodies such as KMPDC and the Nursing Council.	Agree
267		**Dr Joash Auka**	Include a consequential amendment to section 33(5) of the Social Health Insurance Act, 2023 directing accreditation appeals to the Health Care Tribunal, and state expressly that the Tribunal's decisions on accreditation bind the Social Health Authority for empanelment purposes.	Appeals against decisions of the accreditation body are directed to the Health Care Tribunal under this Bill, while section 33(5) of the Social Health Insurance Act directs appeals against the same accreditation decisions to the SHA Dispute Resolution Tribunal. The accreditation body under the SHI Act and the Authority created by this Bill are one and the same, so two competing appellate routes will produce jurisdictional conflict and forum-shopping.	Reject
268		**George Okoth Osimbo**	In clause 85(2), insert the words "or remit the matter to the Authority for reconsideration with appropriate directions" after the word "vary".	Remittal is a well-established administrative law remedy allowing specialised decision-makers to reconsider matters after correction of legal or	**Reject:** the concerns of the stakeholder are already covered under clause 84 (4).

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				procedural errors, strengthening procedural fairness.	
269		**Collins Omollo; Kinyua Murithi; Rural & Urban Private Hospitals Association of Kenya (RUPHA); Dr Ghalib Moseti Abdillahi**	Harmonise the appeal periods: substitute "thirty days" for "twenty-one days" in clause 85(1) so that clauses 85(1) and 95 are consistent (and correspondingly in clauses 46(3), 47(3), 54(4), 63(4) and 64(3)).	The Bill prescribes two different periods for the same appeal — twenty-one days under clauses 46(3), 47(3), 54(4), 63(4), 64(3) and 85(1), and thirty days under clauses 94(1) and 95. A facility acting on clause 95 may find its appeal met with an objection founded on clause 85(1). Certainty as to the period within which a right of appeal must be exercised is a minimum requirement of fair administrative action under Article 47.	**Reject**
270	**Clause 87 – Funds of the Authority**	**IDinsight Dignity Initiative**	Insert a proviso: "Provided that the Authority shall, in each financial year, apply a dedicated allocation of not less than one per cent of its funds to the measurement of patient satisfaction under this Act."	Measurement duties without budgets go unmet. Ring-fencing a small allocation makes the monitoring obligation operable.	The committee noted the comment for further consideration.
271		**Kenya Medical Association (KMA)**	Include a ring-fenced funding floor for the Authority's core patient-safety functions, and earmarked transition funding support for KMPDC and other affected regulators.	KMPDC and allied regulators face an anticipated reduction in facility-inspection fee revenue as this function transfers to the Authority.	The committee noted the comment for further consideration.

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272		**Fatma Kasyoka Said**	Provide for predictable and sustainable financing through adequate parliamentary appropriations; strengthen financial accountability through robust internal controls, regular reporting, independent audits and compliance with the Public Finance Management Act; clarify revenue-generating powers so that fees are transparent, reasonable and do not compromise regulatory independence or restrict access; require publication of audited financial statements and annual financial reports; and clarify the respective financial responsibilities of the national and county governments so that funding the Authority does not impose unfunded obligations on counties.	Comparative experience demonstrates that effective healthcare quality authorities require predictable public financing, sound financial management, transparent reporting and strong accountability mechanisms.	The committee noted the comment for further consideration.
273		**Levis O. Wandolo**	Restore section 40(g) of Cap. 253A (KMLTTB's fee-setting authority) and provide alternative funding within the Bill's financial provisions.	Deleting KMLTTB's fee-setting authority creates an unfunded mandate, eliminating the Board's revenue without alternative funding, contrary to Article 201(d) on public finance accountability.	Reject
274	**Clause 92 – Annual report**	**IDinsight Dignity Initiative**	Delete clause 92(3)(a) and substitute: "(a) data on quality improvement,	A national average hides county variation. Disaggregated annual reporting to Parliament makes the equity commitment	**Reject**

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			patient outcomes, patient satisfaction and health system performance, disaggregated by county and by sex, age, disability and socio-economic status;"	measurable.	
275		**George Okoth Osimbo**	Insert a new paragraph after clause 92(3)(c): "(d) a report on collaboration undertaken with Health Professional Regulatory Bodies in the development, implementation and monitoring of quality standards and corrective actions during the reporting period."	The Authority should remain accountable for inter-agency coordination where regulatory functions overlap. Annual reporting on collaboration promotes transparency and institutional accountability, consistent with Articles 10, 189 and 232.	**Reject**
276		**Rewam Consultancy**	Require the Authority to publish annual reports on inspection outcomes, licensing decisions and Tribunal rulings in accessible formats, including online dashboards, and introduce a public rating or certification system.	Transparency and public reporting help patients make informed choices and strengthen accountability.	
277	**Clause 93 – Regulations**	**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	Insert a new clause 93(1A) to provide: "Before making Regulations under this section, the Cabinet Secretary shall publish the draft Regulations for a period of not less than thirty days and shall facilitate public participation in accordance with	The substance of the regulatory burden is not in the Bill. Quality standards, facility categories, quality rating, administrative fines, accreditation and inspection procedure, fees and standards for ambulance services and emergency medical treatment are all deferred to	**Reject:** The Statutory instruments Act already provides for the manner of processing statutory instruments.

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			Article 118 of the Constitution, including consultation with associations representing health facilities across all levels of care."	Regulations under clause 93(2), and clauses 44(1)(f), 49(g), 58(5)(j) and 59(h). Facilities therefore face criminal and financial liability under standards whose content they cannot see and on which they have no right to be heard.	
278		**George Okoth Osimbo**	In clause 93(1), insert the words "and in consultation with the relevant Health Professional Regulatory Bodies, County Governments and other relevant stakeholders" immediately after the words "the Board". Delete clause 93(2)(g) (standards of medical laboratories) and clause 93(2)(h) (standards of pharmacies). I Insert the words "in consultation with the relevant Health Professional Regulatory Bodies" into clause 93(2)(j) (emergency medical treatment) and 93(2)(m) (medical aesthetic procedures), and "developed jointly with the relevant Health Professional Regulatory Bodies" into 93(2)(q) (quality of healthcare standards).	Standards governing medical laboratories are already prescribed under Cap. 253A and ISO 15189:2022, and pharmacy standards fall within the PPB's mandate under Cap. 244; concurrent authority creates duplication and conflicting requirements. Administrative penalties affecting constitutional rights should be expressly established by Parliament rather than delegated entirely to subsidiary legislation, contrary to Articles 24 and 94.	**Reject:** The Cabinet Secretary is already under obligation to facilitate public participation of regulations before publication and must table evidence of public participation before parliament.

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			Delete clause 93(2)(t) (administrative fines), or subject it to "the principles of proportionality, fairness and the right to fair administrative action under Article 47 of the Constitution".		
279		**Pharmaceutical Society of Kenya (PSK)**	Replace the reference in clause 93(2)(h) to standards of pharmacies with: "General quality-of-care and patient-safety standards applicable to pharmacy services, developed in consultation and concurrence with the Pharmacy and Poisons Board, excluding professional practice, scope of practice, licensing of pharmacy premises and regulation of health products."	The Authority may set facility-wide quality requirements, but pharmacy-specific standards must remain linked to the specialist regulator to preserve technical coherence and Kenya's medicines-regulatory capacity.	**Reject**
280		**Lab Medicine Society of Kenya (LMSK)**	Amend clause 93(2)(g) to read: "Standards of medical laboratories, made in consultation with the Kenya Medical Laboratory Technicians and Technologists Board."	The Cabinet Secretary may prescribe "standards of medical laboratories" by Regulation with no reference to KMLTTB, notwithstanding that KMLTTB already sets professional and technical standards for laboratory practice under Cap. 253A.	Reject
281		**Kinyua Murithi**	Delete clause 93(1)(m) (medical aesthetic procedures) and clause 93(1)(l) (alternative and traditional medicine).	Medical procedures, including aesthetic procedures, are regulated by KMPDC. The standards — quality, safety,	Reject

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				effectiveness — for anything marketed as a medicine, including alternative and traditional medicine, should remain with the PPB or its successor; cultural aspects of alternative and traditional medicine should remain where they currently reside.	
282		**Kennedy Kinyua**	Set principles and maximum limits for administrative sanctions in the Act. Require public participation, regulatory-impact assessment, county consultation, involvement of professional regulators and patient groups, and tabling before Parliament in accordance with the Statutory Instruments Act. Regulations should be published before commencement of the affected obligations.	The Bill delegates critical matters — fees, administrative fines, categories, quality standards, inspection procedures and accreditation — to regulations without sufficient statutory ceilings or consultation requirements.	Accept
283		**Dr Ghalib Moseti Abdillahi**	Amend clause 93(1) to require consultation with the statutory professional regulatory bodies, the Council of County Governors and the public before Regulations are made, and provide that Regulations prescribing standards for a particular profession or service be made on the recommendation of the regulator responsible for that profession or service.	Clause 93(2) confers twenty-one heads of regulation-making power, including quality standards, facility categories, quality rating, scope-related standards for numerous services and administrative fines. Much of the operative content of this legislation will sit in Regulations.	Reject for reasons given above

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284		**Kenya Union of Clinical Officers (KUCO)**	Insert an express limitation that regulations shall not vary a statutory professional scope, transfer a county function, or derogate from another Act unless expressly authorised by primary legislation; and require consultation with counties and affected regulators.	Protects legislative certainty and prevents major institutional changes being effected through subsidiary legislation. Constitution Article 94(6); Statutory Instruments Act.	Reject
285		**Kenya Medical Association (KMA)**	Insert a mandatory review of the Act and its Regulations at intervals of three to five years, explicitly triggered by technological change, reported to Parliament.	A framework of this kind requires a built-in mechanism to keep pace with clinical and technological change; the Bill relies solely on the ordinary Regulation-making power for updates, with no mandated periodic review.	Reject
286		**Fatma Kasyoka Said**	Introduce a statutory requirement for periodic review of the Act and its implementation.	Ensures the legal framework remains responsive to emerging healthcare needs and international best practices.	Reject
287	**Clauses 94–95 – Review and appeal**	**George Okoth Osimbo**	In clause 94(3), insert the words "Unless the Authority or the Tribunal determines that suspension is necessary in the interest of justice or to prevent irreparable prejudice." Insert a new subsection empowering the Authority or Tribunal, on application and where sufficient cause is shown, to grant interim	An automatic refusal to suspend administrative decisions may render the right of review illusory where immediate implementation causes irreversible harm. The amendment strengthens access to justice and gives effect to Articles 47, 48 and 50.	Reject

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			relief or a stay of implementation pending determination of the review or appeal where implementation would occasion irreparable prejudice and does not pose an immediate risk to public health or patient safety.		
288	**Clause 96 – Confidentiality**	**Kenya Medical Association (KMA)**	Require clause 96 to expressly require compliance with the Data Protection Act, 2019, and subject any secondary use of Comprehensive Integrated Health Information System data, including for artificial-intelligence training, to purpose limitation, consent and anonymisation requirements and a documented data protection impact assessment.	The Authority will hold sensitive, patient-identifiable adverse-event and complaint data. Patients' rights as data subjects should not be left unaddressed in a Bill that otherwise emphasises patient rights extensively.	Agree
289		**George Okoth Osimbo**	Substitute the words "to the extent that it considers necessary" with "in accordance with the Constitution, the Data Protection Act, the Health Act and any other applicable written law".	The current wording grants the Authority unrestricted discretion to disclose confidential information. The amendment aligns the provision with Article 31 of the Constitution, the Data Protection Act, 2019 and the confidentiality obligations governing patient health information.	Accept
290		**Kennedy Kinyua**	Replace the discretion with a necessity-and-proportionality test grounded in law. Distinguish public	The Authority may disclose information whenever it "considers necessary" — a	Accept

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			facility-level information from identifiable patient or staff data. Require lawful purpose, minimum necessary disclosure, security safeguards, retention periods, breach response, audit logs and de-identification for publication.	subjective test that does not expressly apply the Constitution, the Data Protection Act, the Digital Health Act, access-to-information law, professional privilege or data-minimisation principles.	
291		**Kinyua Murithi**	Delete clause 96.	The Authority is bound by Article 35 of the Constitution and the Access to Information Act to share information in its possession unless exempted under section 6 of that Act.	Reject
292		**Lydia Nyawira Mburia**	Create tamper-proof ICT healthcare records management systems ensuring security, confidentiality, safe storage, custody and preservation of confidential and classified documents; and ensure periodic health records and ICT audits to ascertain compliance with records safety, storage, preservation and confidentiality.	Confidentiality obligations require supporting technical and audit infrastructure, not merely a statutory duty.	**Accept.** This however can be achieved at the facility level.
293	**Clauses 97–98 – Offences and general penalty**	**Kenya Medical Association (KMA)**	Apply a corresponding and proportionate reduction to the penalties under clauses 48, 55 and 98; introduce tiered penalties by facility category; and insert a general proportionality clause requiring the Authority to have regard to facility size, ownership	The clause 18(2) penalty was reduced from up to fifty million shillings or ten years' imprisonment to a fine of up to ten million shillings only, and now sits beside unchanged, harsher penalties for administrative breaches —	Reject

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			structure, prior compliance history and severity of breach.	unlicensed operation (up to ten million shillings or five years), operating under a revoked licence (up to twenty million shillings or ten years) and the general penalty (up to ten million shillings or ten years). A systemic patient-safety failure should not be punished more lightly than an administrative licensing lapse.	
294		**Dr Ghalib Moseti Abdillahi**	Amend clause 98 to provide a materially lower general penalty and to require the court to have regard to the gravity of the contravention, whether it was deliberate, whether patients were exposed to harm, and the category and resources of the facility. Provide expressly that minor administrative non-compliance shall ordinarily attract a written warning, a corrective action plan and a reasonable compliance period before any penalty is imposed.	A general penalty of that magnitude, applied by default to any unspecified contravention, does not distinguish an administrative lapse from conduct that endangers patients. Clause 68 already provides a graduated administrative response, and the criminal provisions should be reserved for conduct at the upper end of that scale.	**Reject:** The penalty under clause 98 is similar to the penalty under clause 18 and is necessary to effect compliance with the provisions of this Bill.
295		**George Okoth Osimbo**	In clause 97(1)(b), insert the word "lawful" immediately before the word "directions". Substitute clause 98 to provide that "where no specific penalty is provided under this Act, a person	Criminal liability should only arise from failure to comply with lawful directions issued within the Authority's statutory mandate. The current blanket penalty is disproportionate and inconsistent with the	Reject for reasons stated above

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			shall be liable, upon conviction, to a fine not exceeding one million shillings or imprisonment for a term not exceeding one year, or to both, unless a higher penalty is expressly prescribed under this Act."	constitutional principles of fairness and proportionality under Articles 24, 27, 47 and 50.	
296		**Pharmaceutical Society of Kenya (PSK)**	Create proportionate categories of non-compliance. Minor and first-time administrative failures should attract improvement notices or proportionate administrative penalties; criminal sanctions should apply only to deliberate, fraudulent, repeated or reckless conduct creating a serious risk of harm. Require written reasons and stated penalty-assessment factors.	A graduated enforcement model promotes corrective quality improvement and complies with constitutional requirements of proportionality, fair administrative action and a fair hearing.	**Agree:** This is already provided for in the Bill under clause 68
297		**Kennedy Kinyua**	Confine criminal offences to clearly defined intentional, fraudulent, reckless or seriously harmful conduct. Use notices and proportionate administrative sanctions for minor non-compliance, with statutory ceilings and appeal rights. Reduce the general penalty and specify sentencing factors including harm, culpability, cooperation and repeat conduct.	The general penalty of up to KES 10 million or ten years' imprisonment may apply to unspecified contraventions and is disproportionate for technical or reporting failures. The phrase "ought to know" in clause 97 may criminalise negligent error without a clear materiality threshold.	**Reject** for reasons provided above
298		**Kenya Environmental**	Amend the offences clause:	Disproportionate criminal sanctions and high facility	**Reject** for reasons given above

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		Health and Public Health Practitioners Union (KEHPHPU)	"Offences related to failure to comply with HRH standards or norms shall be classified by severity and intent. For first-time or non-wilful breaches (e.g. inadvertent staffing shortfalls, minor reporting lapses), the Authority shall issue corrective orders, require submission of a remedial action plan, or impose administrative fines as specified in regulations. Criminal liability shall be reserved for wilful misconduct, gross negligence resulting in serious harm, or repeated failure after prior corrective orders. Regulations shall define offence categories, sanction ranges, and mitigating factors (e.g. resource constraints, good-faith efforts)." Separately, amend the enforcement clause so that breach of provider-safety or welfare provisions (including failure to provide PPE, safe staffing, or to protect reporting providers) constitutes an offence attracting corrective orders, suspension of accreditation or fines.	liability discourage reporting of near-misses or unintentional breaches, undermining a culture of safety. Proportionality is a legal principle of fair administrative action. Conversely, without explicit penalties for breaches of provider-safety provisions, facilities have no incentive to comply and protect staff wellbeing.	
299		**Dr Royronald Ochieng Ongong'a**	Adopt a tiered liability model distinguishing system-level failure (procurement, staffing,	A punitive framework that holds individual practitioners criminally and financially liable	Reject for reasons given above

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			infrastructure, equipment maintenance) from individual professional negligence, with liability for the former directed to facility management, the County Government or the National Government entity. Cap monetary penalties on individual practitioners at levels proportionate to typical earnings in the cadre, and reserve custodial penalties strictly for proven gross negligence, recklessness or wilful misconduct. Introduce a statutory good-faith defence and an express good-faith immunity clause protecting practitioners who acted reasonably within the standard of care given the resources actually available. Replace automatic punitive escalation with a restorative, phased quality-improvement model: notice of non-conformance, a defined remediation period with technical support, and escalation only for repeated or wilful non-compliance.	for outcomes substantially caused by system-level failures beyond their control is fundamentally unfair and will incentivise concealment of errors and near-misses, drive qualified professionals out of under-resourced public facilities, and deepen an already acute human-resource-for-health shortage — directly counter-productive to the Bill's own patient-safety objective.	
300		**Awuor Linet Owino**	Include legal protections shielding practitioners from liability when quality metrics drop due to verified institutional shortages of reagents, equipment failures, or State funding delays.	Public and low-cost private laboratories routinely suffer delayed procurement of reagents, broken equipment and erratic power supply due to lack of government funding. By threatening facility closures,	Reject

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				criminal penalties and disciplinary action for "compromised quality", the Bill unjustly criminalises frontline laboratory technologists for failures caused by State underfunding.	
301		**Health Unions Caucus (KUCO/KCOA); BCMGA; Scovia Adema; Judy Mso; Ken Ochoggia; Maramba Morena; Emmanuel Chiboya; KUNAD; KNUMLO; Chacha Omahe**	Delete or substantially soften the criminal penalty provisions (originally up to KES 50 million or 10 years' imprisonment for failing to uphold quality assurance standards) and replace them with a graduated, learning-oriented enforcement framework.	Criminalisation encourages cover-ups, discourages voluntary reporting of errors or near misses, and undermines mechanisms such as Maternal and Perinatal Death Surveillance and Response (MPDSR) and facility Quality Improvement Teams. International experience — for example the UK NHS — shows punitive regulation leads to defensive practice; the NHS has since shifted to a "Just Culture" that balances accountability with learning.	Reject for reasons given above
302	**Clause 99 – Transitional provisions**	**Rural & Urban Private Hospitals Association of Kenya (RUPHA)**	In clause 99(2), substitute "twenty-four months" for "one year". Insert a new clause 99(5) as follows: "A certificate of registration, licence or accreditation held under any written law immediately before the commencement of this Act shall remain valid until the Authority	Every health facility in the country must be re-registered, licensed and accredited within twelve months, through an Authority that is not yet established and whose staff are being transferred from the bodies it replaces. Clause 58(6) allows ninety days	**Agree:** This is already provided for under clause 99 of the Bill.

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			determines an application made under this Act in respect of that health facility, and no offence under section 48(3) shall arise in respect of a health facility whose application is pending determination by the Authority." In clause 99(3), substitute "subsection (2)" for "subsection (1)".	to determine an accreditation application and no period at all is fixed for registration or licensing, while clause 48(3) makes operating without a licence an offence carrying a fine of up to ten million shillings or imprisonment for five years. A facility whose application is pending is therefore exposed to criminal liability by reason of administrative delay it cannot influence. The defective cross-reference in clause 99(3) also casts doubt on whether the extension power can lawfully be exercised at all.	
303		**Dr Maria Ogaya Gerald**	Correct the contradiction in clause 99: subsection (1) deems existing facilities registered while subsection (2) requires them to apply afresh within a year, and subsection (3) refers to "the period specified in subsection (1)" when the period is in subsection (2).	That is a drafting error, and as it stands it is not clear whether a facility needs to reapply or not.	Reject: there is no contradiction in the two clauses. Clause 99 (1) deems all health facilities registered under the previous legal regime to be valid while clause 99 (2) requires compliance with this law within one year. These provisions are aimed at ensuring a smooth transition to the new legal regime.
304		**Kennedy Kinyua**	State clearly that existing registration remains valid for a defined transition period and specify whether conversion or re-registration is required. Require a published transition plan, inventory	Clause 99(1) deems existing facilities registered while clause 99(2) appears to require the same facilities to apply for registration within one year. Clause 99(4) automatically transfers staff of	**Reject:** this is aimed at ensuring that the staff previously working under Directorates responsible for the registration and licensing of health facilities are transitioned to the Authority to avoid

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			of functions and records, continuity of pending cases, preservation of employment rights and consultation with affected regulators and unions. Delete the phrase "any relevant regulatory body" in clause 99(4) or list the specific institutions and posts affected.	KMPDC or "any relevant regulatory body" — an undefined and potentially extensive group.	redundancies.
305		**Kenya Medical Association (KMA)**	Precede the transfer of staff under clause 99(4) with a joint capacity assessment between the Cabinet Secretary and the affected regulatory bodies, a defined consultation process, and protection of affected staff's accrued terms and benefits.	KMA recognises a managed transfer is the more practical course, since leaving facility-regulation staff within KMPDC once the mandate moves would risk rendering them redundant; a structured process safeguards staff and institutional continuity.	**Reject**
306		**Pharmaceutical Society of Kenya (PSK)**	In clause 99(4), delete the words "or any relevant regulatory body". Alternatively, expressly exclude the Pharmacy and Poisons Board and require prior consultation with the affected regulator, compliance with employment law and the written consent of the affected employee before any transfer.	PPB requires adequate inspectors, pharmacists and technical staff to continue regulating medicines, pharmacy professionals and premises. The amendment protects institutional continuity and employment rights.	Reject for reasons above
307		**Kenya Union of Clinical Officers (KUCO)**	Delete or substantially revise clause 99(4). Any transfer of functions and staff must follow a clear statutory transition plan, consultation with affected regulators and employees,	Avoids destabilising regulators, arbitrary transfer of staff and institutional loss of specialised expertise.	The comment is noted by the committee for further consideration.

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			protection of accrued labour rights and an explicit mapping of functions.		
308		**Dr Ghalib Moseti Abdillahi**	Amend clause 99 to include transitional provisions addressing the transfer of registers, records and assets; the disposal of pending applications and disciplinary proceedings; and the treatment of fees already paid.	Clause 99(4) transfers staff without any provision for the transfer of records, assets, registers, accrued fee streams, or pending disciplinary and licensing matters. It is unclear what becomes of a matter part-heard before a council on the commencement date.	Reject
309		**George Okoth Osimbo**	Insert a new subsection providing that all licences, registrations, accreditations, approvals and certifications lawfully issued by Health Professional Regulatory Bodies before commencement shall remain valid until their expiry and shall not require fresh approval solely by reason of the coming into force of this Act.	Protects vested rights, ensures regulatory continuity and prevents disruption of healthcare services or unnecessary duplication of licensing and accreditation processes.	Accept: This is already covered in the Bill.
310		**Lab Medicine Society of Kenya (LMSK)**	Delete clauses 99 and 100 and insert a savings clause preserving all existing registrations, licences, accreditations and ongoing disciplinary proceedings under Cap. 253A.	No savings or transitional clause exists for current KMLTTB registrations, practising and superintendency licences, accreditations, or pending disciplinary proceedings.	Reject
311		**Levis O. Wandolo**	Retain KMLTTB licensing and provide a transition framework for existing licences and registrations.	Retroactive nullification of 8,200+ licences violate the legitimate expectation protected	Reject: The amendments are necessary for purposes of separating the regulation of health facilities

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				by Article 47; professionals face prosecution under section 19 of Cap. 253A for "unregistered practice".	from that of healthcare professionals
312		**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah Mercy et al.; Walter Lesaatin; Sheero M.**	Delete clause 99(2) (cited as 101(2)): "All health facilities registered before the commencement of this Act, shall be deemed to have been registered under this Act."	To align with the Authority's proper mandate as an accreditation body rather than a registration and licensing body.	Agree: This is already provided for in the Bill.
313		**Victor Osoo**	Review the transitional provisions.	It is unclear whether the other regulatory authorities will be deemed dead upon establishment of this Authority; the Bill creates duplication of roles and anxiety among professionals in practice.	Reject: The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals
314		**Kenya Medical Association (KMA); Rewam Consultancy; Francis Tauwo; Kennedy Kinyua**	Phase implementation over at least 24–36 months, beginning with baseline registration, capacity assessment and high-risk patient-safety standards; pilot the inspection, rating and incident-reporting systems before national rollout; and provide grants or ring-fenced improvement financing for public and low-resource facilities.	Requiring all facilities to re-register within one year may overwhelm both providers and the Authority. Phased implementation based on facility level and county readiness is more realistic.	**Reject:** the period of one year is sufficient for the transition.
315	**Clause 100 and Second Schedule – Consequential**	**Health Unions Caucus (KUCO/KCOA); KNUMLO; Aidah**	Delete items 1–10 and 19–37 of the Second Schedule.	To align the Bill with the Authority's proper mandate, strengthen the quality assurance framework by making the	Reject: The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare

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	amendments (general)	**Mercy et al.; Walter Lesaatin; Sheero M.**		Authority an oversight body, provide a two-tier quality assurance framework, and avoid conflict with other laws.	professionals
316		**Kennedy Kinyua**	Undertake a profession-by-profession functions matrix before enactment. Preserve professional registration, licensing, discipline, ethics, continuing professional development, scopes of practice and approval/inspection of training institutions. Commence each repeal only when replacement regulations, systems, staff and appeal mechanisms are operational. Include a savings clause for licences, proceedings, inspections and disciplinary matters already underway.	The Schedule removes facility-regulatory functions from multiple professional Acts, but some amendments also alter professional-practice licensing language. The combined effect may be uncertain, particularly for clinical officers, nurses, laboratory personnel and allied health professionals, and repeals may create gaps before the Authority is operational.	This is noted by the committee for further consideration.
317		**Kenya Union of Clinical Officers (KUCO)**	Insert the provision: "Except where expressly provided by an Act of Parliament, nothing in this Act shall derogate from the statutory functions of a professional regulatory body relating to professional training, registration, licensing, scope of practice, professional standards, continuing professional development or discipline."	Consistency across all professional statutes — Nurses and Midwives Act, Nutritionists and Dieticians Act, Physiotherapists Act, Radiographers Act, PHOTC Act and related laws — prevents piecemeal erosion of professional self-regulation.	Reject: The Bill already separates the regulation of health facilities from that of healthcare professionals. Further, the functions of the Quality Healthcare and Patient Safety Authority are clearly provided for and does not extend to the regulation of professionals which is a duty left to professional bodies.

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			Apply one consistent principle across cadres: the quality Authority regulates institutional quality and accreditation; statutory regulators retain professional qualification, registration, licensing, scope, competency, CPD and discipline.		
318		**Kenya Union of Clinical Officers (KUCO)**	Insert a new devolution/non-recentralisation safeguard: "Nothing in this Act shall be construed as transferring, assuming, diminishing or otherwise altering a function assigned to a county government under the Constitution. National quality standards shall be implemented through the level of government constitutionally responsible for the relevant function and through consultation and cooperation between the two levels of government."	Directly protects county functional and institutional integrity under Articles 6(2), 174, 186–190 and the Fourth Schedule.	Reject: The Bill already separates the regulation of health facilities from that of healthcare professionals. Further, the functions of the Quality Healthcare and Patient Safety Authority are clearly provided for and does not extend to the regulation of professionals which is a duty left to professional bodies.
319		**Dr Ghalib Moseti Abdillahi; Kenya Medical Association (KMA)**	Retain a concurrent clinical inspection power for the professional councils, or provide expressly for joint inspection between the Authority and the relevant council. Requested amendments relate to Second Schedule items 4, 5, 20, 22 and 25.	Item 22 repeals section 15 of Cap. 253 and item 25 repeals section 17, removing KMPDC's power to register and license health institutions. Item 20 deletes paragraphs (k), (l) and (m) of section 4 of Cap. 253 and item 19 deletes the definition of "health institution".	Reject: The Bill already separates the regulation of health facilities from that of healthcare professionals. Further, the functions of the Quality Healthcare and Patient Safety Authority are clearly provided for and does not extend to the regulation of professionals which is a duty left to professional bodies.

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				These repeals leave the councils with no inspection power of any kind over the premises in which their own registrants practise. Clinical standards and premises standards are severed with no bridge between them: a council may find a practitioner unfit yet have no means of inspecting the theatre in which the conduct occurred; the Authority may inspect the theatre without competence to assess the clinical practice within it.	
320		**Dr Joash Auka**	On Second Schedule items 19–28, add a transitional clause requiring KMPDC to hand over live facility registers and pending applications to the Authority within a fixed period, with pro-rata reconciliation of fees already collected.	The consequential amendments repeal KMPDC's facility-related functions and its institutional-insurance role under section 15A of the Medical Practitioners and Dentists Act, transferring them wholesale to the Authority with no transitional handover mechanism. Section 15A currently funds part of the Council's oversight capacity through institution-related fees.	Agree: The transfer of functions to the Authority means an automatic transfer of all the live registers and therefore sufficiently covered by the Bill.
321		**Dr Joash Auka**	On Second Schedule item 5 (amendment of section 60 of the Health Act), insert a mandatory reporting requirement obliging the Authority to transmit inspection and enforcement data to the Director-	The amendment narrows the Director-General's obligation from inspecting and evaluating the standard of performance to merely monitoring conduct, while the Cabinet Secretary's	Reject

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			General for the purposes of section 5 monitoring.	duty under clause 5 to ensure continuous quality improvement remains unchanged — leaving a continuing statutory duty without an information source to discharge it.	
322		**Dr Joash Auka**	On Second Schedule item 9 (repeal of section 153 of the Public Health Act), confirm the content and continued necessity of the repealed provision before assent, and retain or replace it if the Bill's own provisions do not fully substitute for it.	Section 153 is repealed outright with no substitute provision identified. If it provided nuisance or insanitary-premises closure powers, the Bill's own closure powers under clauses 8(2)(b) and 79(1)(a) may not fully replicate that function, particularly for premises falling outside the Bill's narrower definition of 'health facility'.	Reject: The inspection of health facilities will be undertaken by the Quality Healthcare and Patient Safety Authority established under clause 26 of this Bill.
323		**Kenya Union of Clinical Officers (KUCO)**	On Second Schedule items amending the Clinical Officers Act (Cap. 253E), especially sections 5, 20–24 and 31: oppose any amendment that weakens the Clinical Officers Council's professional self-regulatory mandate. In particular, deletion of section 20(5)– (8) removes the Council's current powers over registration, licensing and inspection of Clinical Officer medical centres and clinics. If Parliament centralises generic facility licensing, it must preserve	The Council is the specialist statutory regulator for Clinical Officers. Facility quality regulation must not become a vehicle to erode Clinical Officers' lawful professional autonomy or create unequal treatment between cadres.	Reject: The Bill already separates the regulation of health facilities from that of healthcare professionals. Further, the functions of the Quality Healthcare and Patient Safety Authority are clearly provided for and does not extend to the regulation of professionals which is a duty left to professional bodies.

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			the Council's professional-practice, training, scope, standards, discipline and profession-specific inspection role, and establish mandatory joint inspection/accreditation arrangements.		
324		**Kenya Union of Clinical Officers (KUCO)**	On Second Schedule amendments to the Health Act sections 48 and 60: do not narrow KHPOA or the regulators' mandates without an express rationalization scheme. If the Authority assumes system-quality accreditation, preserve regulators' professional oversight and require joint or coordinated inspections. On the amendment to Health Act section 20, do not delete the cooperative role of the national health department and professional regulatory bodies — instead add the Authority as a quality partner without extinguishing existing actors.	Prevents regulatory gaps during transition and preserves specialist competence.	Reject: The Bill already separates the regulation of health facilities from that of healthcare professionals. Further, the functions of the Quality Healthcare and Patient Safety Authority are clearly provided for and does not extend to the regulation of health professionals which is a duty left to professional bodies.
325	**Second Schedule – Pharmacy and Poisons Act (Cap. 244)**	**Pharmaceutical Society of Kenya (PSK)**	Delete paragraph 10 of the Second Schedule in its entirety and retain the relevant provisions of section 3B of the Pharmacy and Poisons Act. Delete paragraph 14 and retain section 23. Delete paragraph 15 and retain section 23A. Delete paragraph 16 and retain section 44(1) (mb).	Paragraph 10 removes pharmacies, including hospital and clinic pharmacies, from PPB's statutory inspection and licensing function; PPB must supervise the final points at which medicines are stored, supplied and dispensed. Section 23 is a core safeguard against	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation

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				illegal or unsuitable pharmacy premises. Section 23A allows PPB to act promptly where pharmacy conditions threaten medicine quality, lawful supervision or patient safety. Section 44(1) (mb) is the statutory rule-making foundation for standards and practice of pharmacy.	
326		**Regulatory Affairs Professionals Society of Kenya (RAPSK)**	Maintain section 3B of Cap. 244 under paragraphs (i) and (j) as currently drafted. Maintain sections 20, 23 and 23A of Cap. 244 as currently drafted. Expressly preserve the Pharmacy and Poisons Board's mandate over pharmaceutical retail outlets and pharmaceutical warehouses.	The amendment takes away PPB's authority to regulate the manufacturing, registration, distribution and sale of Health Products and Technologies, contrary to the ambition of Kenya becoming a regional manufacturing hub. PPB must attain WHO Global Benchmarking Tool Maturity Level 3 status, achievable only if PPB remains the single responsible national regulatory authority. Repealing sections 20, 23 and 23A removes PPB's power to ensure adherence to Good Pharmacy Practice and Good Distribution Practices. The definition of 'health facility' does not include pharmaceutical warehouses and retail outlets, leaving a regulatory gap.	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation.

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327		**Collins Omollo**	In Second Schedule item 10(b), insert the words "and replacing with a new paragraph (i) to read as follows: approve and license the premises for the practice by pharmacists in manufacturing, importing and exporting agents, wholesale and distributors". Delete item 14 and replace it so that section 23 of Cap. 244 is amended (not repealed) by adding the words "pharmacists in manufacturing, importation and exportation, wholesale and distributorship" after the word "pharmacist" in subsection (1) and deleting subsection 1A. Delete item 15 and replace it so that section 23A is amended by adding the same words and deleting the words "or pharmaceutical technologists" from subsection (1). Delete item 16 and replace it so that section 44(1) is amended by adding the words "in manufacturing, importation and exportation, wholesale and distributorship" after the word "pharmacy".	Regulation of pharmacists in manufacturing, importation and exportation, wholesale and distributorship will remain under the Pharmacy and Poisons Board under the proposed amendment in item 10(a); it is therefore critical to provide for that regulation for public health and safety. Repealing sections 23 and 23A entirely would leave the business of a pharmacist in manufacturing, importation and exportation, wholesale and distributorship unregulated, which would be a danger to public health and safety. PPB should retain powers to set standards of practice in those areas, while the Authority regulates retail and hospital pharmacies.	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation
328		**Kinyua Murithi**	Delete paragraph (i) of subsection (3) in Second Schedule item 10(c).	Item 10(c) paragraph (i) empowers the Board to prescribe	Reject: The amendments are necessary to separate facility

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			Insert a new paragraph (renumbering the document) repealing section 20 of the Pharmacy and Poisons Act. Insert a further new paragraph repealing paragraph (d) of subsection (1) of section 21 of the Pharmacy and Poisons Act.	the scope of practice of pharmacists and pharmaceutical technologists and categories of pharmacies — a responsibility clause 18(1)(c) allocates to the Cabinet Secretary; preserving it will create overlaps and confusion, and ranking of facilities rests with the Authority under clause 58(1)(a). Sections 20 and 21(1)(d) deal with the display of names and registration certificates in premises, which would introduce overlapping control of pharmacies between PPB and the Authority; the published Bill proposed repeal of section 20, but the National Assembly committee amended it instead.	regulation from health professionals' regulation
329		**Dr Lucy Mecca**	Clarify the transfer and allocation of regulatory functions relating to pharmacy premises, and expressly define the respective responsibilities of the Authority and the Pharmacy and Poisons Board in relation to licensing, inspection and enforcement of pharmacy premises.	The Bill amends section 2 of the Health Act to include pharmacies within 'health facility', amends sections 3A and 3B of Cap. 244 and repeals sections 23 and 23A, but does not state which functions are transferred or how the two regulators will exercise their mandates. This will eliminate uncertainty, prevent regulatory conflict and ensure continuity in the regulation of pharmacy services.	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation

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330		**Dr Joash Auka**	Note that item 10 removes pharmacies, including those in hospitals and clinics, from the premises-licensing mandate of the Pharmacy and Poisons Board under section 3B(2)(j) of Cap. 244, and items 14 and 15 repeal sections 23 and 23A of that Act.	Part of a wider pattern in which the Second Schedule goes further than the Bill's own stated purpose requires.	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation
331	**Second Schedule – Medical Laboratory Technicians and Technologists Act (Cap. 253A)**	**Lab Medicine Society of Kenya (LMSK)**	Delete the proposed amendment to section 5 and restore the original section 5(1) – (2). Delete the proposed amendment to section 40 in its entirety and retain paragraph (g). Revert the Part IV heading to "PART IV — PROVISIONS RELATING TO PRIVATE PRACTICE". Revert section 20 in full to the original text. Reinstate section 21 and add that no medical laboratory shall be licensed, registered or accredited as a health facility unless it operates under a licensed superintendent. Revert section 22(1), restoring "and place of business".	Item 40 narrows the Board's statutory object from training, business, practice and employment to training and professional conduct alone. Section 40(g) — the Board's power to make Regulations on the practice, standards, enforcement and inspection of medical laboratories — is deleted in full with no replacement anywhere in the Bill. The Part IV heading change is not cosmetic: it recasts the qualification, licensing and standards provisions away from their private-practice basis. Item 42 deletes the requirement to hold a valid practising certificate and the five-year supervised-practice requirement.	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation.

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			Reinstate section 25 in full. Revert section 30(6) so that appeal lies to the High Court.	Section 21 (superintendent licensing) and section 25 (technical standards for equipment, reagents, services and employment terms, backed by an offence provision) are repealed in full with no replacement. Deleting "and place of business" severs the statutory link between a named professional and a specific laboratory. Transferring appellate jurisdiction to a generalist tribunal removes access to a forum with established jurisprudence on professional discipline.	
332		**Levis O. Wandolo**	On clause 42(a) of the Second Schedule, restore the original text of section 5(1) of Cap. 253A (deleting 'business, practice and employment' should be reversed). On clause 42(b), retain section 5(2)(d) or clarify its scope. On clause 44, reinstate section 20. On clause 45 (new section 21), align the language with the Bill's clause on transfer of licensing power. On clause 47, retain section 25.	Removal of 'business, practice and employment' erodes KMLTTB's mandate over professional conduct, entrepreneurship and employment standards essential for diagnostic integrity. Deleting section 5(2)(d) likely removes biosafety and equipment oversight, contravening WHO International Health Regulations (2005) Annex 4 and section 6 of the Occupational Safety and Health Act, risking laboratory-	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation.

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			On clause 48, restore section 40(g). Mandate ISO 15189 compliance in the accreditation standards, and retain KMLTTB disciplinary tribunals in place of the repeal of section 26.	acquired infections. Repealing section 20 creates a legal vacuum: professionals cannot obtain Board-issued certificates required under the new section 21 while the Bill transfers power to the Authority. Repealing section 25 deregulates private laboratories. Deleting section 40(g) creates an unfunded mandate contrary to Article 201(d). Generic quality standards without laboratory input risk diagnostic failures given Kenya's WHO Tier-2 Laboratory Status (2023). KMLTTB resolved 147 misconduct cases in 2024.	
333		**David Wekesa**	Delete the amendment to section 5 of Cap. 253A unless demonstrably consequential; delete the amendment to the Part IV heading; delete the amendment to section 20 unless strictly consequential and expressly preserving KMLTTB authority; delete clause 43 (repeal of section 21) in its entirety; delete or revise	Repealing section 21 can materially alter the existing KMLTTB practising-licence framework and creates uncertainty over who issues, renews, suspends or restores practising certificates. Repealing an existing professional-regulatory provision without a fully equivalent replacement risks weakening profession-specific accountability. Substituting 'Tribunal' for the	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation.

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			the amendment to section 22 so that KMLTTB remains the sole professional licensing authority; delete clause 45 (repeal of section 25) unless an equivalent or stronger professional safeguard is expressly preserved; delete clause 46 (substitution of "Tribunal" for the High Court in section 30) unless the Senate expressly establishes that the Tribunal has no original professional-disciplinary jurisdiction and only hears matters after exhaustion of KMLTTB's statutory process; and delete clause 47 (amendment of section 40) unless the affected paragraph is proven redundant and KMLTTB retains equivalent regulation-making authority.	High Court changes the appellate route and could expose a laboratory professional to a parallel or altered disciplinary pathway outside the established professional disciplinary law.	
334		**Lilian Kerubo Nyarieko; Fridah Mukiri John; Ndege James Muchira**	Reconsider the proposed repeal of section 21, the amendment of section 25 and the deletion of paragraph (g) of section 40 of Cap. 253A to ensure no regulatory gap is created in the oversight of medical laboratories, and expressly clarify that the establishment of the Authority does not extinguish or override KMLTTB's specialised	If KMLTTB's specialised statutory authority is removed without an equally clear replacement mechanism, it becomes unclear who determines whether a laboratory is technically fit to operate, who conducts laboratory-specific inspections, who enforces laboratory-specific standards,	Reject: The amendments are necessary to separate facility regulation from health professionals' regulation.

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			statutory mandate.	and who holds the laboratory professional accountable for technical practice.	
335		**James Kago**	Preserve the laboratory superintendent licensing framework.	The superintendent role promotes professional accountability, quality management and career progression within medical laboratories; preserving it would strengthen laboratory governance and enhance patient safety.	Reject: This can be provided for under regulations.
336		**Hadija Bisharo**	Require mandatory peer-review vetting and KMLTTB Board examination before any foreign-trained laboratory professional is licensed.	The proposals in the Bill would fast-track foreign-trained laboratory staff without KMLTTB Board examination, diluting training standards; the KMLTTB career path must be respected and protected.	Reject: The purpose of the Bill is to separate health facility regulation from health professionals regulation.
337	**Second Schedule – Medical Practitioners and Dentists Act (Cap. 253)**	**Kenya Union of Clinical Officers (KUCO)**	Any transfer of generic facility registration and licensing must be accompanied by a precise delineation that preserves professional regulation, medical and dental standards, internship accreditation and discipline. Avoid wholesale repeal without a tested transition framework.	Prevents gaps in professional and institutional accountability.	Agree: The Bill seeks to separate health professionals' regulation from health facilities regulation.
338		**Kenya Medical Association (KMA)**	On the amendments to sections 15, 15A and 17 of the MPDA and section 60 of the Health Act, require that inspection of clinical services and the quality-assessor function be	The consequential amendments strip every clinical professional regulator of inspection power over facility premises, while the Authority may appoint inspectors	Reject: the Bill separates the mandates of health professional regulation bodies from the role of the authority which will be to regulate health facilities.

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			conducted by, or in the presence of, a healthcare professional registered with the relevant professional council, with minimum professional qualifications and conflict-of-interest disclosure.	and quality assessors with qualifications it prescribes itself, without requiring any clinical qualification or conflict-of-interest standard.	
339	**New provisions proposed – Healthcare worker rights and safety**	**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Insert a new Part II-A, "Provider Rights and Protections": Every healthcare provider has the right to— (1) a safe and dignified working environment, including protection from occupational hazards, violence, harassment and undue stress, consistent with the OSH Act, 2007 and the Health Act, 2017; (2) timely access to PPE, infection prevention training, occupational health services and psychosocial support; (3) fair remuneration, rest breaks and leave; (4) confidential and protected channels to report safety concerns without retaliation; (5) participation in safety and quality improvement committees; (6) ongoing professional development with protected time; and (7) clear information on and	Provider welfare underpins patient safety. International norms and Kenyan statutes (Health Act, OSH Act) recommend explicit provider rights to ensure safe work conditions and reporting protections. Nurses and other healthcare workers face high stress, burnout and mental health challenges directly affecting patient safety and quality of care; WHO and ILO guidance and Kenyan workplace health statutes emphasise mental health support.	Reject: Health workers rights are already protected under the Employment Act and the Occupational Safety and Health Act.

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			coverage by professional indemnity arrangements. The Authority shall develop regulations specifying standards and procedures to implement these rights in accreditation and inspection. Insert a further clause requiring every facility to establish or facilitate access to psychosocial support services for healthcare providers, including confidential counselling, peer-support forums, stress management programmes and referral pathways for specialised mental health care.		
340		**Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU)**	Under Human Resource Standards in the accreditation criteria, add: (a) adequate staffing levels and skill mix based on recognised guidelines; (b) a functioning occupational health programme for staff including risk assessments, PPE provision, immunisations, health surveillance and mental health support; (c) an established safety and health committee with provider representation meeting at least quarterly with documented hazard identification and corrective actions; (d) policies for reporting safety	Accreditation currently focuses on patient metrics and lacks staff welfare and safety measures. Safe staffing, occupational health programmes and reporting mechanisms are essential for quality care and align with section 12 of the Health Act and WHO guidance.	Agree: The issues raised by the stakeholder can be effectively addressed through regulations.

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			concerns and incidents by staff, with evidence of no-retaliation enforcement; and (e) facilities for staff rest and lactation stations for nursing mothers as per the Health Act, 2017.		
341		**Pharmaceutical Society of Kenya (PSK)**	Insert a new clause after clause 19: "Rights and safety of healthcare workers — (1) Every health facility shall provide and maintain, so far as is reasonably practicable, a working environment that is safe, healthy, adequately resourced and free from avoidable occupational hazards, violence, harassment and victimisation. (2) A health facility shall establish confidential and non-punitive systems through which healthcare workers may report hazards, patient-safety incidents and near misses. (3) No healthcare worker shall be subjected to retaliation for making a report in good faith under subsection (2). (4) This section shall be implemented in accordance with the Occupational Safety and Health	Safe care depends on a safe workforce. Explicit recognition encourages facilities to invest in occupational safety, psychological safety and learning systems, and responds to member feedback that worker rights should not be diluted within a general risk-management clause.	Reject: Health workers rights are already protected under the Employment Act and the Occupational Safety and Health Act.

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			Act, 2007 and applicable labour laws."		
342		**Dr Royronald Ochieng Ongong'a**	Insert a dedicated Part on Healthcare Worker Safety and Wellbeing guaranteeing a safe and adequately resourced working environment, appropriate PPE, and reasonable staffing and workload standards; impose an explicit statutory duty on facilities and the responsible national/county authorities to supply the reagents, consumables and functional equipment necessary for safe discharge of diagnostic and clinical duties; provide protection from workplace violence, harassment and hostility with a reporting and redress mechanism; and recognise access to occupational mental-health support and burnout-prevention programming as part of the Authority's quality and safety mandate.	Article 41 of the Constitution guarantees every worker the right to fair labour practices and reasonable working conditions. A statute that regulates the conduct of healthcare workers in exhaustive detail while remaining silent on the conditions under which they work falls short of this constitutional standard and risks entrenching an unsustainable model of quality assurance built on individual exhortation rather than systemic support.	Reject: Health workers rights are already protected under the Employment Act and the Occupational Safety and Health Act.
343		**Francis Tauwo; Beatrice Mwanzia; Isaac Kiplimo Sambu; Kennedy Kinyua**	Insert explicit whistleblower protection provisions covering confidentiality, protection from victimisation and anonymous reporting channels; and require employers to provide adequate staffing, a conducive working environment, essential medicines	Healthcare workers may fear retaliation when reporting unsafe practices; the Bill places extensive obligations on facilities but offers limited protection to workers operating under resource constraints.	Partly agree: Health workers rights are already protected under the Employment Act and the Occupational Safety and Health Act.

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			and equipment, protection from workplace violence and mental health support.		
344	**New provisions proposed – Emerging modalities, digital health and AI**	**Kenya Medical Association (KMA)**	Insert a new provision defining artificial intelligence, algorithms and software-as-a-medical-device, requiring Authority certification or validation of AI-based clinical tools before deployment, and mandating a documented human-in-the-loop sign-off for AI-assisted diagnosis or treatment. On clause 93(2)(k), insert baseline statutory standards for telemedicine now, covering data security, informed consent for remote care, prescribing limits and identity verification, together with a cross-border and mutual-recognition framework extending at least to the East African Community. Require interoperable electronic health records, laboratory information systems, electronic incident reporting and secure data management.	The Bill is silent on artificial intelligence, algorithms and software-as-a-medical-device, which play an expanding role in clinical care and currently fall entirely outside its framework. Leaving all telemedicine standards to future Regulations creates a prolonged regulatory gap for a rapidly growing mode of care delivery. Electronic systems reduce errors, improve communication and enhance continuity of care.	Reject: the Bill already addresses emerging medical aspects such as telemedicine.
345		**Fatma Kasyoka Said**	Extend the scope of application to expressly cover telemedicine, digital health services, home-based care, community health services, mobile outreach programmes and Primary	Emerging healthcare delivery models are insufficiently addressed. Comprehensive regulation covering all major delivery models improves	Agree: This is already provided for in the Bill.

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			Healthcare; and incorporate provisions on electronic health records, health information systems and data quality standards consistent with the Digital Health Act.	regulation of digital healthcare and enhances quality assurance.	
346		**Francis Tauwo**	Require compliance with the Digital Health Act, the Data Protection Act and cybersecurity standards for electronic health records, and include explicit standards for telemedicine, artificial intelligence in healthcare and home-based care in the accreditation framework.	The Bill refers to digital reporting but provides little detail on protecting patient information, and the accreditation framework does not address emerging modalities.	Agree
347		**Dr Joash Auka**	Insert a savings clause suspending enforcement against medical aesthetic procedures, telemedicine services, and alternative and traditional medicine until the relevant Regulations under clause 93(2)(k)–(m) are gazetted, subject to a fixed backstop period.	These categories are defined and made subject to future Regulations, yet the general offence and penalty provisions already apply in the interim. Enforcement in advance of any operative, gazetted standard creates a real risk of arbitrary or premature enforcement action, particularly against currently informally-regulated practitioners.	Reject
348	**New provisions proposed – Public health emergencies and continuity**	**Kenya Medical Association (KMA)**	Include provisions requiring continuity of quality assurance, patient-safety monitoring, diagnostic quality and infection prevention during disease outbreaks and other public health	The Bill provides no mechanism for maintaining quality and patient safety during public health emergencies, which place additional strain on healthcare systems but require maintenance	Agree: This is sufficiently covered in the Bill.

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			emergencies.	of quality standards.	
349		**Isaac Kiplimo Sambu**	Require all laboratories to implement comprehensive biosafety and biosecurity programmes, conduct risk assessments, maintain emergency preparedness plans for epidemic-prone diseases, provide special PPE for high-risk laboratory work, and establish systems for reporting and managing occupational exposures and laboratory-acquired infections.	Strengthens laboratory and public health emergency response systems and protects both patients and healthcare workers.	Agree: The issues raised however can be effectively addressed through regulations.
350		**Francis Tauwo**	Expressly prohibit denial or delay of life-saving emergency treatment on financial grounds.	Emergency treatment should not be delayed due to inability to pay.	Agree however, the right to emergency treatment is already guaranteed under the Constitution.
351		**The Paramedic Association of Kenya (TPAK)**	Provide for the classification, registration and regulation of ambulances by type, each matched to a defined level of clinical staffing: patient transport vehicles (stable patients only, not dispatched to emergencies); Basic Life Support ambulances staffed by personnel certified at least to Emergency Medical Technician level; and Advanced Life Support ambulances staffed by a registered paramedic. No ambulance should be crewed by a driver alone. Require a single national standard	At present any vehicle described as an ambulance may be dispatched to any emergency regardless of whether its crew is trained and equipped for it. To label a vehicle as ALS without a paramedic on board misrepresents the level of care available to the patient and the dispatcher, and is itself a direct risk to patient safety. The 2026 Performance Audit of Emergency Medical Care Services by the Office of the Auditor-General documented	Agree however the concerns of the stakeholder would be best addressed through regulations.

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			for the specification and construction of ambulances, with paramedic involvement in procurement and specification, and no vehicle (including a donated vehicle) accepted or deployed as an ambulance unless it meets the national standard. Organise emergency ambulance services as identifiable departments with their own establishment and budget, headed at county level by a Chief Paramedic. Require any private organisation providing paramedic or emergency medical services to hold a Private Paramedic Service Authority issued jointly by the Ministry of Health and KMPDC, conditional on a clinical governance framework, safe operations, sound medicines management and employment of appropriately educated and registered clinicians.	serious systemic failings including ambulances that are non-functional, unstaffed, poorly maintained or lacking essential supplies.	