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REPUBLIC OF KENYA

THE NATIONAL ASSEMBLY

THIRTEENTH PARLIAMENT – FIFTH SESSION – 2026

DIRECTORATE OF DEPARTMENTAL COMMITTEES

DEPARTMENTAL COMMITTEE ON HEALTH

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

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CHAIRPERSON'S FOREWORD

This report contains the proceedings of the Departmental Committee on Health on its consideration of The Quality Healthcare and Patient Safety Bill, 2025 (National Assembly

Bill No. 41 of 2025) sponsored by the Hon. Leader of the Majority Party, which was published on 12th July, 2025. The Bill was read the First Time in the House on Thursday,14th August 2025, and thereafter committed to the Departmental Committee on Health for consideration and reporting to the House pursuant to the provisions of Standing Order 127.

The Bill has hundred (100) clauses and seeks to give effect to Article 43(1)(a) of the Constitution on the right to the highest attainable standard of health. It further seeks to provide for the responsibility of the national and county governments in the realisation of quality of healthcare for patients; to provide for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, registration, licensing and accreditation of health facilities and to provide for the setting of standards for quality of healthcare.

Following the placement of an advertisement in the print media on 22nd August 2025 seeking public and stakeholder views on the Bill pursuant to Article 118(1) (b) of the Constitution and Standing Order 127(3), the Committee received submissions from sixteen (16) stakeholders, including the Ministry of Health (MOH), Office of the Attorney General and Department of Justice (OAG), and the National Gender and Equality Commission (NGEC), Kenya Accreditation Service(KENAS),Pharmacy and Poisons Board(PPB), Kenya Association of Pharmaceutical Industry(KAPI),Kenya Healthcare Federation (KHF),Pharmaceutical Society of Kenya (PSK), Pharmaceutical Society of Kenya, Nairobi Branch, Kenya National Commission on Human Rights(KNCHR),Kenya Medical Practitioners and Dentists Council(KMPDC), Kenya Health Professions Oversight Authority (KHPOA), the Law Society of Kenya (LSK), Mr. George Otieno Agal, Dr. Kipruto Chesang and Dr. Richard Mogeni, Consultant Obstetrician and Gynaecologist.

The Committee also engaged various stakeholders, including the Ministry of Health (MOH), KMPDC, the Clinical Officers Council, the Nursing Council of Kenya, the Kenya Medical Laboratory Technicians and Technologists Board, the Office of the Attorney General and Department of Justice (OAG and DOJ), and the Kenya Law Reform Commission (KLRC), to make oral submissions on the Bill.

The Committee is grateful to the Offices of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its sittings. The Committee further wishes to thank all stakeholders who submitted memoranda on the Bill.

Finally, I wish to express my appreciation to the Honourable Members of the Committee and the Committee Secretariat for their valuable contributions towards the consideration of the Bill and the production of this Report

On behalf of the Departmental Committee on Health and pursuant to the provisions of Standing Order 199 (6), it is my pleasant privilege and honour to present to this House the Report of the Committee on its consideration of the Bill.

It is my pleasure to report that the Committee has considered the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025) and has the honour to report back to the National Assembly with the recommendation that the Bill be **approved with amendments as reported by the Committee**.

HON. DR. NYIKAL JAMES WAMBURA, CBS, MP
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

CHAPTER ONE

1.0 PREFACE

1.1 Establishment and Mandate of the Committee

1. The Departmental Committee on Health is one of the Departmental Committees of the National Assembly established under Standing Order 216 whose mandates pursuant to the Standing Order 216 (5) are as follows:

   a) To investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned ministries and departments;

   b) To study the programme and policy objectives of ministries and departments and the effectiveness of the implementation;

   c) on a quarterly basis, monitor and report on the implementation of the national budget in respect of its mandate;

   d) To study and review all legislation referred to it;

   e) To study, assess and analyse the relative success of the ministries and departments as measured by the results obtained as compared with their stated objectives;

   f) To investigate and inquire into all matters relating to the assigned ministries and departments as they may deem necessary, and as may be referred to them by the House;

   g) To vet and report on all appointments where the Constitution or any law requires the National Assembly to approve, except those under Standing Order 204 (Committee on Appointments);

   h) To examine treaties, agreements and conventions;

   i) To make reports and recommendations to the House as often as possible, including recommendations of proposed legislation;

   j) To consider reports of Commissions and Independent Offices submitted to the House pursuant to the provisions of Article 254 of the Constitution; and

   k) To examine any questions raised by Members on a matter within its mandate.

1.2 Subjects under the Committee

2. In accordance with the Second Schedule of the Standing Orders, the Committee is mandated to consider matters related to health, medical care and health insurance, including universal health coverage.

1.3 Oversight

3. In executing its mandate, the Committee on Health oversees the:
   i. State Department for Medical Services and;
   ii. State Department for Public Health and Professional Standards.

1.4 Committee Membership

4. The Departmental Committee on Health was constituted by the House on 27th October 2022 and comprises the following Members:

Chairperson
Hon. Dr. Nyikal James Wambura, MP
Seme Constituency
ODM Party

Vice-Chairperson
Hon. Ntwiga, Patrick Munene MP
Chuka/Igambang'ombe Constituency
UDA Party

Hon. Owino Martin Peters, MP
Ndhiwa Constituency
ODM Party

Hon. Muge Cynthia Jepkosgei, MP
Nandi (CWR)
UDA Party

Hon. Wanyonyi Martin Pepela, MP
Webuye East Constituency
Ford Kenya Party

Hon. Kipng'ok Reuben Kiborek , MP
Mogotio Constituency
UDA Party

Hon. (Dr) Robert Pukose, MP
Endebess Constituency
UDA Party

Hon. Kibagendi Antoney, MP
Kitutu Chache South Constituency
ODM Party

Hon. Julius Ole Sunkuli Lekakeny, MP
Kilgoris Constituency
KANU

Hon. Maingi Mary, MP
Mwea Constituency
UDA Party

Hon. Mathenge Duncan Maina, MP
Nyeri Town Constituency
UDA Party

Hon. Lenguris Pauline, MP
Samburu (CWR)
UDA Party

Hon. Oron Joshua Odongo, MP
Kisumu Central Constituency
ODM Party

Hon. (Prof.) Jaldesa Guyo Waqo, MP
Moyale Constituency
UPIA Party

Hon. Mukhwana Titus Khamala, MP
Lurambi Constituency
ODM Party

1.5 Committee Secretariat

5. The Committee is facilitated by the following staff secretariat:

Mr. Adan Gindicha
Principal Clerk Assistant II-HOD

Mr. Ellam Omuhinda
Clerk Assistant III

Ms. Gladys Jepkoech Kiprotich
Clerk Assistant III

Ms. Marlene Ayiro
Principal Legal Counsel I

Ms. Faith Chepkemoi
Legal Counsel II

Mr. Hiram Kimuhu
Fiscal Analyst II

Mr Eric Lungai
Hansard Reporter II

Ms. Sheila Chebotibin
Principal Serjeant-At-Arms

Ms. Abigael Muinde
Research Officer III

Ms. Mercylyn Kerubo
Audio Recording Officer

Mr. Hillary Mageka
Media Relations Officer III

CHAPTER TWO

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

2.1 BACKGROUND ON THE BILL

6. The Quality Healthcare and Patient Safety Bill, 2025 (hereinafter referred to as "the Bill"), sponsored by the Hon. Leader of the Majority Party was referred to the Departmental Committee on Health for consideration after First read on Thurdsay, 14th August 2025.

7. The Bill seeks to give effect to Article 43(1)(a) of the Constitution on the right to the highest attainable standard of health. It further seeks to provide for the responsibility of the national and county governments in the realisation of quality of healthcare for patients; to provide for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, registration, licensing and accreditation of health facilities and to provide for the setting of standards for quality of healthcare

2.2 OVERVIEW OF THE BILL

8. Part I (clause 1 to 6) provides for preliminary matters including the short title, the objects of the Act and guiding principles on the implementation of the law when it becomes operational. The objects of the law are to guarantee patient rights and patient safety, provide a framework for the setting of standards for healthcare services and health facilities, improve the quality of healthcare services and health outcomes; ensure health facilities provide healthcare services in a manner that guarantees high-quality care, safety, effectiveness and efficiency and establish mechanisms for the implementation and monitoring of standards of quality healthcare.

9. It also provides various definitions such as quality of healthcare and accreditation for quality of healthcare among others. It further sets out the role of the Cabinet Secretary responsible for health as well as those of the county governments in implementation of the Act.

10. Part II (clause 7 to 25) outlines the rights of patients who seek healthcare services from a health facility. These rights are to be read with those provided for under the Health Act, Cap. 241. The rights include right to safe and quality care, right to timely and effective care, right to safe and accessible health facilities, right to safe processes and practices, right to care by a qualified health professional, right to dignity and equity, right to information and decision making, right to be heard and right to safe and quality health products and technologies. A health facility that fails to comply with the provisions on patient safety and quality assurance measures commits an offence and is liable to a fine not exceeding fifty million shillings or to imprisonment for a term not exceeding ten years.

11. Part III (clause 26 to 41) provides for the establishment of the Authority as the primary regulator of health facilities for purposes of quality of healthcare, its functions, powers; the composition, term of office, functions and qualifications of the Board of Directors of the Authority. It further provides for the appointment of a Chief Executive Officer and the staff of the Authority.

12. Under this Part, the functions of the Quality Healthcare and Patient Safety Authority are 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 of healthcare standards; (e) inspect health facilities for compliance with the quality of 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 of healthcare; (h) accredit health facilities for purposes of empanelment and contracting under section 33 and 34 of the Social Health Insurance Act; (i) maintain a register of registered, licensed and accredited health facilities, (j) inspect and accredit health facilities for purposes of internship and training; (k) promote public awareness on quality of healthcare including on patient rights; (l) build capacity on matters related to quality of healthcare; (m) provide policy advice and make recommendations to the Cabinet Secretary on matters related to quality of healthcare; (n) advise the Cabinet Secretary and county governments on the standards of quality of healthcare for health facilities; and (o) perform such other functions as may be as necessary for the promotion of the objects of this Act or prescribed by any other written law.

13. Under clause 29, the Quality Healthcare and Patient Safety Authority is to be managed by a Board of Directors consisting of— (a) a chairperson appointed by the President; (b) the Principal Secretary in the Ministry for the time being responsible for matters relating to quality of healthcare standards or a representative designated in writing; (c) the Principal Secretary for the National Treasury or a representative designated in writing; (d) the 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 improvement; management and quality (g) one person appointed by the Cabinet Secretary, not being a public officer, to represent healthcare providers; (h) one person appointed by the Cabinet Secretary to represent the public; and (i) the Chief Executive Officer, who shall be an ex officio member of the Board.

14. Part IV (clause 42 to 71) provides for the process of registration, licensing and accreditation of health facilities including timelines and prerequisites for grant of certificates for registration, licensing and accreditation, the validity period and instances where the Authority can order suspension or revocation of the certificates. Accreditation is based on compliance with quality standards and will be valid for two (2) years. Fraudulent accreditation attracts fines up to Kshs. one million or imprisonment of up to one year.

15. The Part also provides for consequences of operating health facilities which are not registered or licensed. This will constitute an offence punishable by a fine of up to Kshs. ten million or imprisonment of up to five (5) years. Whereas operating a health facility whose licence has been revoked attracts a fine of twenty million shillings or imprisonment for a term not exceeding ten years.

16. The Part further sets out the quality improvement in a health facility, the procedure for quality scoring and rating, award of performance rating and monitoring of compliance by the Authority. The Part requires health facilities to implement quality improvement plans, undergo scoring and rating, be subject to sanctions for non-

compliance including fines, warning or closure), and be entered into a national register.

17. Part V (clause 72 to 82) provides for the conduct of inspections including unannounced visits and investigations by the Authority including the appointment, qualifications, code of conduct and powers of inspectors. The Part empower inspectors and the Authority to suspend unsafe services or close facilities in cases of imminent danger. The Part also criminalizes obstruction of inspectors', an offence which will attract penalties including fines of upto Kshs. two million or imprisonment of up to two years.

18. Part VI (clause 83 to 86) provides for the establishment of a Health Care Tribunal, its composition and its role in adjudicating disputes arising out of matters envisaged by the Bill and the administration and enforcement of disputes in the health sector once it is enacted. The Tribunal shall be a specialized forum for healthcare disputes and will determine appeals against Authority decisions and complaints relating to patient rights and safety.

19. Part VII (clause 87 to 92) provides the sources of funds of the Authority including appropriations by the National Assembly, donations, and grants; the modalities on annual reporting by the Authority and handling of the accounts of the Authority including the audit of its finances.

20. Part VIII (clause 93) provides for the delegation of power to the Cabinet Secretary in the Ministry responsible for health, in consultation with the Board of Directors of the Authority, to make regulations for the better carrying into effect of the provisions of the Act and the general provisions such as accreditation and categorization of health facilities.

21. Part IX (clause 94 to 98) provides for the right of review of a decision made under the Act, appeal, offences such as such as falsification of records, obstruction of inspectors and the general penalty.

22. Part X (clause 99 to 100) provides for the transitional provisions in relation to the registration of existing health facilities as well as consequential amendments to other statutes in light of the introduction of this Bill. These amendments are necessary since the Bill seeks to separate the regulation of health facilities from that of the practitioners.

23. The First Schedule provides for the conduct of the business and affairs of the Board of the Authority in terms of minutes, quorum among others.

24. The Second Schedule provides the consequential amendments which ensure harmonization of related laws including the Health Act, the Pharmacy and Poisons Act, Mental Health Act, Medical Practitioners and Dentists Act, Medical Laboratory Technicians and Technologists Act, Nutritionists and Dieticians Act, Counsellors and Psychologists Act, Physiotherapists Act, Clinical Officers (Training, Registration and Licensing) Act, Radiographers Act, Public Health Officers (Training, Registration and Licensing) Act, Occupational Therapists (Training, Registration and Licensing) Act, Nurses and Midwives Act, Health Records and Information Managers Act and the Social Health Insurance Act.

CHAPTER THREE

3.0 CONSIDERATION OF THE BILL BY THE COMMITTEE

3.1 LEGAL PROVISION ON PUBLIC PARTICIPATION

25. Article 118 (1) (b) of the Constitution of Kenya provides as follows—

"Parliament shall facilitate public participation and involvement in the legislative and other business of Parliament and its Committees."

26. Standing Order 127(3) provides that—

"The Departmental Committee to which a Bill is committed shall facilitate public participation on the Bill through an appropriate mechanism, including—

(a) inviting submission of memoranda;
(b) holding public hearings;
(c) consulting relevant stakeholders in a sector; and
(d) consulting experts on technical subjects.

27. Standing Order127(3A) further provides that—

"The Departmental Committee shall take into account the views and recommendations of the public under paragraph (3) in its report to the House."

3.2 PUBLIC PARTICIPATION IN THE REVIEW OF THE BILL

28. The Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 Of 2025)which was published on 12th July,2025. Pursuant to Standing Order 127(1), the Bill was referred to the Departmental Committee on Health, having been read the First Time in the House on Thursday,14th August 2025.

29. Pursuant to the aforementioned provisions of the Constitution and the Standing Orders on public participation, the Committee, through local daily newspapers (Nation and Standard) of Friday, 22nd August 2026, published an advertisement inviting the public to submit memoranda on the Bill.

30. The Committee also sought comments on the Bill from relevant stakeholders, namely the Ministry of Health, the Office of the Attorney General, the Department of Justice, and the Kenya Law Reform Commission, vide letter dated 24th September 2025.

31. Further, vide a letter dated 22nd October 2025, the Committee invited the Ministry of Health, the Office of the Attorney General and Department of Justice (OAG & DOJ), and the Kenya Law Reform Commission (KLRC) to submit memoranda on the Bill, which were considered at a meeting held on Tuesday, 28th October 2025. Subsequently, the Committee held a further engagement with the Ministry of Health on Friday, 21st November 2025 in Machakos County. The Committee also meet Kenya Health Professions Oversight Authority (KHPOA) ,KMPDC, the Clinical Officers Council, the Nursing Council and the Kenya Medical Laboratory Technicians and Technologists Board in Mombasa County on 19th March 2026.

3.3 SUBMISSIONS ON THE BILL

32. The Committee received submissions through oral presentations and written memoranda from the following institutions:

1. The Ministry of Health (MOH),
2. The Office of the Attorney General and Department of Justice (OAG and DOJ)
3. The National Gender and Equality Commission (NGEC)
4. Pharmaceutical Society of Kenya (PSK) Nairobi Branch
5. Kenya Accreditation Service (KENAS)
6. Pharmacy and Poisons Board (PPB),
7. Kenya Association of Pharmaceutical Industry (KAPI),
8. Kenya Healthcare Federation (KHF),
9. Kenya Health Professions Oversight Authority (KHPOA)
10. Law Society of Kenya (LSK)
11. Pharmaceutical Society of Kenya (PSK),
12. Kenya National Commission on Human Rights (KNCHR)
13. Kenya Medical Practitioners and Dentists Council (KMPDC)
14. Mr. George Otieno Agal
15. Dr. Richard Mogeni, Consultant Obstetrician and Gynaecologist
16. Dr. Kipruto Chesang
17. The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)
18. Nursing Council of Kenya (NCK)
19. Clinical Officers Council

33. THE MINISTRY OF HEALTH (MOH)

The Ministry of Health vide a letter dated 4th August 2025 submitted as follows:

Background

The Government of Kenya has identified healthcare as one of the core pillars of its Bottom-Up Economic Transformation Agenda (BETA). In the Plan, a number of commitments have been identified towards the delivery of Universal Health Coverage (UHC). These interventions include:

(a) A fully publicly financed primary healthcare comprising of preventive, promotive, curative, palliative and rehabilitative services;
(b) Integrating Information Communication and Technology systems to enhance telemedicine and health management information systems;
(c) Ring-fencing funds for healthcare from facility improvement funds to allocations from the National Treasury in collaboration with County Governments;
(d) Setting up an emergency medical treatment fund to cater for emergency, cancer treatment and referrals; and
(e) Providing Social Health Insurance coverage for all of Kenyans without exclusion in the policy of "Leaving No One Behind".

The commitments are in line with the Kenya Vision 2030 which, under the social pillar, envisions a nation that is healthy and prosperous. The commitments further, align with the Sustainable Development Goal (SDG), Number 3 on "Good Health and Well-Being" which seeks to ensure "healthy lives and promote well-being for all at all ages". In order to achieve this, a number of success indicators are to be realized including the reengineering of health care services and the provision of functional, efficient and sustainable health infrastructure network across the country. Pursuant to the commitments identified under BETA, the Government put in place four (4) pieces of legislation to provide the legislative framework upon which UHC will be realized as follows:

(a) The Primary Healthcare Act (No. 13 of 2023) to provide a framework for the delivery of, access to and management of primary health care;
(b) The Digital Health Act (No. 15 of 2023) to provide for the establishment of the Digital Health Agency; to provide a framework for provision of digital health services; and to establish a comprehensive integrated digital health information system;
(c) The Facility Improvement Financing Act (No. 14 of 2023) to provide for public health facility improvement financing and the management and administration of facility improvement financing; and
(d) The Social Health Insurance Act (No. 16 of 2023) to establish the framework for the management of social health insurance; to provide for the establishment of the Social Health Authority; and to give effect to Article 43(1)(a) of the Constitution.

2.The Quality Healthcare And Patient Safety Bill, 2025

Despite these progressive frameworks, a significant challenge persists: many health facilities and healthcare providers are yet to fully grasp the principles and benefits of quality healthcare. Premised on the need to ensure the quality of healthcare services and the protection of the safety of patients, the Ministry of Health, in collaboration with the County Governments and the Office of the Attorney General and Department of Justice, has developed a draft Quality Healthcare and Patient Safety Bill, 2025.

In line with Article 10 of the Constitution, the Ministry subjected the Bill to stakeholder engagements and public participation where interested stakeholders and members of the public submitted comments and views, and made representations regarding the proposed Bill; which were thereafter reviewed and incorporated into the Bill, where appropriate. The Ministry subsequently sought the approval of the Office of the Attorney General & Department of Justice on the Bill; which was granted vide the Office's letter Ref: AG/LDD/119/1/110 and dated 23rd July, 2025.

3. Cabinet Approval on the Quality Healthcare and Patient Safety Bill, 2025

Following the Attorney General's approval, the Ministry developed a Cabinet Memorandum on the Quality Healthcare and Patient Safety Bill, 2025, seeking the Cabinet's approval on the tabling of the Bill in Parliament. The Cabinet Office subsequently, vide the letter Ref: CAB/GEN. 3/1/1 VOL.XLIV/45 and dated 29th July, 2025, communicated the Cabinet's approval on the Bill for its onward transmission to Parliament.

Following the Cabinet's approval, the Office of the Attorney General and Department of Justice has, vide the letter Ref: AG/LDD/119/1/110 and dated 31st July, 2025, forwarded the approved Bill to the Leader of the Majority Party in the National Assembly for

introduction in Parliament. The Ministry then forwarded the following documentation for the Committee's consideration:

(a) Report of the Public Participation and Stakeholder Engagement conducted for the Quality Healthcare and Patient Safety Bill, 2025;
(b) Invitation letters to stakeholders to engagement forums for the Bill;
(c) Attendance Registers for the public participation exercise and stakeholder engagement conducted for the Bill;
(d) Feedback forms for the public participation exercise and stakeholder engagement forums;
(e) Matrix of the comments raised during stakeholder engagement forums on the Bill;
(f) Matrix of the comments raised during public participation on the Bill; and
(g) Matrix of comments raised by County Directors of Health on the Bill.

Further, when the Cabinet Secretary appeared before the Committee on 28th October 2025, the Cabinet Secretary requested the Hon. Members to support the Bill so that we can have a framework for the regulation of quality healthcare and the realization of patient rights and safety and submitted as follows:

(a) Article 43 of the Constitution enshrines every individual's entitlement to the highest attainable standard of health, encompassing access to healthcare services, including reproductive health, and guarantees emergency medical treatment.
(b) Article 21(2) mandates the State to take legislative, policy and other measures, including the setting of standards, to achieve the progressive realisation of the right to the highest attainable standard of health. These constitutional provisions have elevated public expectations for improved quality in health service delivery.
(c) The Government is undertaking legal reforms intended to provide the legislative basis for the realization of Universal Health Coverage (UHC), including through the enactment of:

    (i) The Primary Healthcare Act (No. 13 of 2023);
    (ii) The Digital Health Act (No. 15 of 2023);
    (iii) The Facility Improvement Financing Act (No. 14 of 2023); and
    (iv) The Social Health Insurance Act (No. 16 of 2023).

(d) Despite these progressive frameworks, a significant gap exists in the provision of quality healthcare services and the protection of the safety of patients, which are a critical determinant of the overall health and well-being of a nation's population.
(e) The Ministry called upon the Committee to note that, as a country, we have never had a national body responsible for quality healthcare and patient safety. This gap has led to inconsistencies in the quality of healthcare services provided and has resulted in various regulatory bodies independently setting standards for health facilities within their respective mandate, resulting in a fragmented system with no overarching oversight and weak enforcement mechanisms. For instance, the Kenya Medical Practitioners and Dentists Council, Clinical Officers Council, Kenya Medical Laboratory Technicians and Technologists Board, and the Nursing Council of Kenya all operate independently in regulating healthcare institutions. This fragmented regulatory framework leads to inconsistent standards, and accountability gaps, ultimately compromising patient safety and quality of healthcare services.
(f) The current fragmented regulatory framework has left some healthcare services unregulated. For instance, there are currently no nationally recognized standards for ambulance services, which poses risks to patient safety, quality of healthcare, and coordination during medical emergencies. Additionally, the fragmentation in the

health sector has led to significant gaps in the oversight of emerging healthcare practices and procedures. As a result, new services often operate in regulatory grey areas, exposing patients and providers to legal uncertainty and potential harm. This regulatory vacuum undermines the ability of existing institutions to provide consistent guidance or recourse when disputes arise.

(g) The presence of multiple regulators overseeing different aspects of healthcare facilities has also made the regulatory environment costly, uncoordinated, and inefficient. Health service providers are often required to obtain multiple licenses from different regulatory bodies, each with their own compliance requirements, timelines, and attendant costs. This fragmented approach results in increased administrative burden and compliance costs for healthcare providers which are ultimately passed on to consumers in the form of increased healthcare charges. These inefficiencies undermine the ease of doing business in the health sector and lead to increase in the cost of healthcare services.

(h) The inadequate regulation and oversight have led to preventable medical errors, poor patient experiences, and suboptimal health outcomes. As a result, there is growing recognition of the need to institutionalize quality and patient safety across all levels of the healthcare system.

(i) In order to promote streamlined regulation of the health sector, consistency in quality, enhanced accountability and patient safety across the healthcare system, there was need to develop the Quality Healthcare and Patient Safety Bill which seeks to establish a globally-acceptable concept of a national entity with the mandate to set, monitor, and enforce healthcare standards at all levels of care. This will strengthen the quality assurance framework and support Kenya's efforts towards achieving Universal Health Coverage by establishing a centralized regulatory authority to ensure that all healthcare practices including newly introduced procedures and services are subject to clear, consistent, and enforceable standards.

(j) The Bill also seeks to introduce the concept of "accreditation of health facilities" in accordance with the globally accepted best practice by setting national quality of care accreditation standards which will guide the proposed Quality Healthcare and Patient Safety Authority in the accreditation of health facilities. These standards play a vital role in promoting quality of healthcare and safeguarding patient rights. They guide the systematic evaluation of facilities against established benchmarks related to service delivery, governance, and patient safety. By ensuring adherence to these standards, accreditation enhances the credibility, efficiency, and accountability of health services, thereby contributing to improved health outcomes and public trust in the system.

(k) The concept and practice of "accreditation" already exists in the country. However, it is not applied in a uniform manner across sectors. Instead, different industries and professions have developed their own accreditation frameworks, each with distinct standards, processes, and outcomes. Within our healthcare system, there are pockets of accreditation carried out by different professional regulators which prescribe different standards for health facilities resulting in a lack of uniformity in accreditation.

(l) The Ministry noted that the concept of accreditation has come to be widely associated with the Kenya Accreditation Service (KENAS) which, as provided under the Kenya Accreditation Service Act (Cap. 496A), 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), SafeCare 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. It is evident that 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. As demonstrated by internationally recognized best practice, 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.

(m) One of the primary functions of accreditation is to institutionalize continuous quality improvement (CQI) within the healthcare system. Health facilities certified by the proposed Quality Healthcare and Patient Safety Authority are required to adhere to evidence-based clinical protocols, maintain adequate infrastructure, and provide safe and effective care. This not only reduces medical errors and adverse events but also improves treatment outcomes and overall patient satisfaction. The process of accreditation also empowers patients to make informed choices by providing them with reliable information about the quality of services across facilities. This fosters public trust locally and internationally in the health system and increases demand for services that meet acceptable standards.

(n) From the perspective of patient rights, accreditation also supports the enforcement of key principles such as informed consent, confidentiality, dignity, non-discrimination, and the right to timely and appropriate care.

(o) In developing this Bill, the Ministry drew upon best practices and conducted extensive stakeholder engagements and public participation across all 47 Counties, in line with Article 10 of the Constitution. Key stakeholders and members of the public were granted the opportunity to submit comments, views, and representations on the Bill. We carefully reviewed the feedback received and amended the Bill, where appropriate, to ensure that it accurately reflects the needs and expectations of our society.

(p) It is also evident that there has been a gap in the uniform regulation of healthcare, which has created room for the entry and practice of quacks. This lack of consistency in regulation has allowed unqualified individuals and unauthorized health facilities to operate within the health sector, often without oversight or accountability. The presence of such quacks undermines patient safety, exposes the public to preventable harm, erodes trust in the health system, and compromises the quality of care and patient safety delivered to citizens.

(q) The proposed Bill seeks to address these challenges by creating a unified regulatory system for the oversight, registration, licensing and accreditation of health facilities, thereby promoting consistency, accountability, and improved healthcare outcomes. It also seeks to establish a unified health sector tribunal to harmonize dispute resolution within the health sector and to serve as a platform to interpret and adjudicate on emerging health issues, thereby reinforcing oversight, fostering innovation within a regulated framework, and safeguarding the rights of all stakeholders.

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

(s) Clauses 7- 25 outlines the rights of patients who seek healthcare services from a health facility. These rights are to be read with those provided for under the Health Act, Cap. 241. The rights include right to safe and quality care, right to timely and effective care, right to safe and accessible health facilities, right to safe processes and practices, right to care by a qualified health professional, right to dignity and equity, right to information and decision making, right to be heard and right to safe and quality health products and technologies.

(t) Clauses 26-41 provides for the establishment of the Authority as the primary regulator of health facilities for purposes of quality of healthcare, its functions, powers; the composition, term of office, functions and qualifications of the Board of Directors of the Authority. It further provides for the appointment of a Chief Executive Officer and the staff of the Authority.

(u) Clauses 42-71 provides for the process of registration, licensing and accreditation of health facilities including timelines and prerequisites for grant of certificates for registration, licencing and accreditation, the validity period and instances where the Authority can order suspension or revocation of the certificates. It also provides for consequences of operating health facilities which are not registered or licensed. It sets out the quality improvement in a health facility, the procedure for quality scoring and rating, award of performance rating and monitoring of compliance by the Authority.

(v) Clauses 72-82 provides for the conduct of inspections and investigations by the Authority including the qualifications and powers of inspectors.

(w) Clauses 83-86 provides for the establishment of a Health Care Tribunal, its composition and its role in adjudicating disputes arising out of matters envisaged by the Bill and the administration and enforcement of disputes in the health sector once it is enacted.

(x) Clauses 87-92 provides the sources of funds of the Authority, the modalities on annual reporting by the Authority and handling of the accounts of the Authority including the audit of its finances.

(y) Clauses 93-100 provides for the delegation of power to the Cabinet Secretary in the Ministry responsible for health, in consultation with the Board of Directors of the Authority, to make regulations for the better carrying into effect of the provisions of the Act and the general provisions such as categorization of ambulances, right of review of a decision and appeal, offences and penalties and the transitional provisions in relation to the registration existing health facilities as well as consequential amendments to other statutes in light of the introduction of this Bill.

(z) The First Schedule provides for the conduct of the business and affairs of the Board of the Authority while the Second Schedule provides the consequential amendments.

In addition, the Ministry of Health made an additional submission in response to the letter dated 22nd October, 2025 referenced NA/DDC/DC-H/2025/99 and the invitation to appear before the Committee to discuss the Bill. The submission clarified the issues raised on 7th October 2025 especially on the consequential amendments made to other health laws. In this regard, the Ministry submitted as follows:

(a) The proposed amendments are intended to align existing health laws with the new structure set out in the Quality Healthcare and Patient Safety Bill, especially in areas related to registration, licensing, and accreditation. These changes are also meant to clearly separate the regulation of health professionals from the regulation of health facilities. This follows international best practice, which promotes fairness and avoids conflicts of interest in regulating the health sector.

(b) Regarding the Health Act (Cap. 241), the Bill expands the definition of several terms. Notably, the definition of *"health facility"* has been broadened to include digital platforms used to provide healthcare services, as well as pharmacies and ambulances. Other health laws, such as the Medical Practitioners and Dentists Act (Cap. 253) and the Clinical Officers (Training, Registration and Licensing) Act (Cap. 253E), attempted to define the terms *health institution*, *clinic*, and *medical centre*, but these definitions were neither consistent nor standardized. The Quality Healthcare and Patient Safety Bill now provides one clear and uniform definition of the term *"health facility"* to harmonize all related aspects under a single law.

(c) The proposed amendments to the Health Act concerning the Kenya Health Professions Oversight Authority (KHPOA) are meant only to align its functions with the proposed Quality Healthcare and Patient Safety Authority. Under Clause 27 of the Bill, the proposed Authority will be responsible for registering, licensing, accrediting and inspecting health facilities. The amendments don't change KHPOA's core role of promoting and regulating inter-professional liaison between statutory regulatory bodies. The changes mainly relate to inspections, dispute resolution, and setting of standards, which will now fall under the proposed Authority's mandate.

(d) For the Medical Practitioners and Dentists Act (Cap. 253), the Quality Healthcare and Patient Safety Bill separates the regulation of health facilities by the Kenya Medical Practitioners and Dentists Council (KMPDC) from the regulation of individual medical practitioners and dentists. Currently KMPDC is responsible for both registering, licensing, and inspecting health facilities, as well as registering and licensing practitioners. The proposed amendment seeks to ensure that the regulation of health facilities is solely assigned to the proposed Authority.

(e) Similarly, the Clinical Officers (Training, Registration and Licensing) Act (Cap. 253E) will be amended to separate the regulation of health institutions from that of clinical officers.

(f) The proposed amendments also seek to assign the role of dispute resolution in the health sector to the proposed Authority, as provided under Clauses 11 and 16 of the Bill. Where parties have exhausted the remedies available before the Authority and are not satisfied with its decision, they may appeal to the Healthcare Tribunal established under Part V of the Bill.

(g) As provided under Clause 84 of the Quality Healthcare and Patient Safety Bill, the Tribunal is mandated to hear and determine all matters relating to the health sector, including disputes between health facilities, patients, healthcare providers, and regulatory bodies. Parties who have exhausted these remedies may thereafter approach the High Court for further redress.

(h) Assured the Committee that all professional regulatory bodies, through their respective Councils, will continue to regulate their respective professionals to uphold integrity and professionalism. These core functions remain unchanged. The only functions being transferred to the proposed Authority are the registration, licensing, accreditation, and inspection of health facilities, as well as the resolution of disputes within the health sector so as to ensure fairness and efficiency.

(i) Called upon the Hon. Members to support the Bill so that we can transform our country's health sector together and ensure the delivery of quality healthcare services to all our patients.

Committee resolution: The Committee noted the comments from the Ministry of Health.

34. **THE PHARMACEUTICAL SOCIETY OF KENYA**

The Pharmaceutical Society of Kenya submitted as follows:

(a) Delete paragraph 19 and 20 of the Second Schedule. Section 23A proposed for deletion relates to the power of the Pharmacy and Poisons Board to register and close premises. Registration and licensing of pharmacy premises ought to be a preserve of the Pharmacy and Poisons Board in line with Kenya's maturity level's goal.

(b) Delete paragraph 21 of the Second Schedule. Consider retaining the current section 44(1)(mb) which currently gives the Cabinet Secretary responsible for health in consultation with the Pharmacy and Poisons Board the power to make rules on the standards and practice of pharmacy. This the role will still be undertaken by the Cabinet Secretary responsible for health under the Bill. The attainment of the ML3 status by Kenya is an ongoing process being undertaken by the Ministry in collaboration with the PPB. The proposed amendment is not only defective but also in breach of Kenya's commitment to international obligations under WHO. While this paragraph proposes to delete section 44 of the Pharmacy and Poisons Act, Cap. 244.

(c) Article 43 of the Constitution provides for social and economic rights which include the right to the highest attainable standard of health including the right to health care services. The health function is devolved, with functions distributed between the National Government and County Governments in the Fourth Schedule. The National Government is tasked with formulation of the Health Policy while the County Governments are assigned the role of managing county health facilities and pharmacies, ambulance services and the promotion of primary health care.

(d) The Health Act, Cap. 241, which seeks to implement the Constitutional provisions on health matters further stipulates that the National Government shall coordinate development of standards for quality health service delivery and promote the use of appropriate health technologies for improving the quality of healthcare.

(e) International instruments that Kenya has ratified also speak to this issue and especially in line with health products and technologies and the practice of pharmacy. WHO recognizes health products and technologies as one of the key building blocks of a health system. For instance, the WHO's Global Benchmarking Tool (GBT) which defines nine core regulatory functions including licensing of premises and regulatory inspection, requires all medicine-handling facilities of member states (manufacturers, wholesalers and retail pharmacies) to be regulated by one regulatory body.

(f) The GBT which classifies national regulatory systems into maturity levels, has classified Kenya at Maturity Level 2 which means Kenya has foundational regulatory structures in place. The aim is to elevate Kenya to ML3 status which means aligning Kenya's ability to independently regulate medical products in line with international good practices.

(g) In line with this, the Pharmacy and Poisons Board in collaboration with the Ministry of Health has made great strides in driving reforms to align the regulatory framework with the WHO standards. This includes establishing quality management systems, digitization of licensing and enhancing post-marketing surveillance.

(h) Attainment of ML3 status for Kenya would be a huge achievement as it would accelerate access to safe and effective medical products through faster approval processes, elevate public trust by ensuring quality and safety in health products and technologies and open up opportunities for mutual recognition arrangements and inclusion into the WHO Listed Authorities networks.

(i) The Bill addresses some of the issues and challenges raised in health sector policies. It has made some progressive proposals, for instance, in clause 18 of the Bill, on patient safety and quality assurance measures, it states that every health facility shall adhere to the scope for healthcare providers employed or contracted by them. This aligns with the proposals around the anticipated Pharmacy Practice legislative framework. However, some suggestions on how to improve the Bill include;-

1. There is need to ensure that, in line with global good practice, regulation of the premises and practice of pharmacists is not separated. This is because the practice is linked to the product held within the premises that is to be dispensed to a patient. Furthermore, Kenya risks losing the ML3 pathway if licensing is split between the Pharmacy and Poisons Board and the proposed Quality Healthcare and Patient Safety Authority. In the UK for example, the Medicines and Healthcare Products Regulatory Agency (MHRA), which is the equivalent of the Pharmacy and Poisons Board in Kenya, undertakes the registration and licensing of pharmacies in order to ensure that all pharmacies in the UK are legally compliant and meet standards for the safe handling and provision of medicines. The scope of this regulation entails regulating the pharmacy premises, the medicines they handle, and the sale of medicines, classifying them into legal categories like General Sales List (GSL) and Pharmacy (P).
2. The process involves an initial inspection and approval, followed by applying for staff licensing and a final inspection and fee payment. Afterward, a mandatory licence to operate as a pharmacy is issued. National Health Service/Care Quality Commission carries out accreditation whose purpose is to demonstrate a pharmacy's commitment to delivering continuous high-quality patient care, setting high standards, and fostering continuous improvement within the National Health Service. It encompasses various aspects, such as accreditation of specific programmes for staff development or quality assurance of services like hygienic preparation of medicines within National Health Service facilities. This involves gathering evidence on whether requirements have been met for roles like training officers and adherence to quality standards, the outcome of which is a voluntary quality benchmark and a route to recognition for practitioners and services within the National Health Service.

3. In line with the above, the PSK urges the Committee to consider recognizing Pharmacy as a unique cadre based on how the healthcare service relating to pharmacy is offered across the world. Furthermore, we propose that registration and licensing of community pharmacies is left to the Pharmacy and Poisons Board or to be carried out jointly with the proposed Quality Healthcare and Patient Safety Authority(Authority). This will be integral in safeguarding Kenya's ML3 goal by preserving this integration. Borrowing from the UK example, we propose that the Authority retains the role of accreditation of pharmacies in line with the standards and guidelines developed by the Cabinet Secretary and Director-General respectively.

Committee resolution: The Committee noted the comments by the PSK. Paragraph 19, 20 and 21 of the Second Schedule are proposed by deletion due to the overall objective of separating the regulation of health facilities from the regulation of healthcare professionals.

35. THE LAW SOCIETY OF KENYA (LSK)

The Law Society of Kenya (LSK) Submitted as follows;

a) Clause 2;

i. The definition of "emergency treatment" in the Health Act (Cap.241)(as amended) can be retained (and the Health Act referred to in the definition).The word 'medical' in 'emergency medical treatment can be done away with as it is superfluous. The definition would therefore read as follows: "Emergency medical treatment" has the same meaning assigned to it under Section 2 of the Health Act.

Alternatively: The definition of "emergency treatment" that is used in the Health Act (Cap. 241) can be expanded, if the sponsor of the bill specifically intends to include in the definition the transportation of patients who require emergency care.

In this case, the proposed definition can read as follows: "Emergency treatment" refers to necessary immediate healthcare that must be administered to prevent death or worsening of a medical situation, and includes healthcare services administered to patients while in transit to or from a health facility.

Justification: The clause fails to capture the urgency of an emergency in its description, and further, is drafted in a way that is quite vague and lacking in clarity. It prevents ambiguity and incorporates the urgency and immediacy of emergency care, which is a defining element of emergencies.

Committee resolution: Not adopted. The proposed definition is more appropriate and is aligned to the Health Act, Cap. 241.

ii. Proposes that in the Health Act, "healthcare professionals" is used instead of "healthcare providers", yet the definition of "healthcare provider" includes a health professional. The better phrase to be used in the definition (as it is all-encompassing), is therefore "healthcare providers".

The proposed definition should read as follows: "Healthcare services" means the prevention, promotion, management or alleviation of disease, illness, injury, and other physical and mental impairments in individuals, delivered by healthcare professionals' providers through the healthcare system's routine health services, or its emergency health services."

Justification: The definition of "healthcare services" in the Health Act, although broad, could benefit from a slight but significant change that would make it more comprehensive. Since the definition of "healthcare services" in the Health Act is also shared by this Bill, this change to the Health Act is recommended. It ensures the definition of "healthcare services" fully captures the broad spectrum of healthcare delivery.

Committee resolution: Adopted with amendment. The definition of the term "healthcare provider" is more comprehensive as it includes a healthcare professional providing healthcare services.

iii. The defined term should be "quality healthcare". The word 'of' in quality of healthcare' should therefore be deleted where appropriate (since there are instances in the Bill where "of" may be correctly used).

Justification: It prevents ambiguity. The phrase being defined is not very clear. The 'Quality of healthcare' can be good, bad, mediocre, or have other descriptors. "Quality healthcare", on the other hand, connotes positive attributes, which may be what the defined terms should be referring to.

Committee resolution: Noted. The minor error will be edited.

b) Clause 3

Reword clause 3(a) as follows:"(a) implement measures that safeguard patient rights and patient safety.

Justification: Laws generally require reasonable measures and standards rather than absolute guarantees, particularly in areas involving risk and human error. One should hesitate to use the word "guarantee" in legislation when it comes to patient rights and safety, but rather, take a more realistic approach that speaks to efforts to ensure that patient rights and safety are emphasized. This is because (as has been acknowledged in the Bill), adverse events can happen in the course of treatment. What then happens to the 'guarantee' of safety that had been promised in the Bill on the occurrence of an adverse event? The patient's safety will already have been breached (thereby nullifying the guarantee),and the only recourse might be some form of compensation or damages.

Committee resolution: Not adopted. The clause is in order as drafted.

c) Clause 5

i. Clause 5(a) should be re-worded as follows: The Cabinet Secretary shall-

a)In consultation with healthcare regulatory bodies or relevant healthcare bodies or agencies develop and ensure implementation of policies, standards, guidelines and protocols that ensure the provision of quality healthcare services including staffing norms and standards".

Justification: It ensures that policies, standards and guidelines are informed by the knowledge and experience of regulatory bodies and other relevant stakeholders.The main issue in this sub-clause is the absence of a requirement for the Cabinet Secretary to act in consultation with other bodies or persons when developing and ensuring standards, protocols, etc. This lack of participation and consultation with relevant healthcare bodies is inadvisable, given the expertise present in, say, regulatory bodies, and further, the clause as drafted deprives itself of the benefit of enrichment through the views of different stakeholders.

Committee resolution: Not adopted. The clause is in order as drafted.

ii. In relation to clause 5(c)(iv), it is paramount to clarify what 'experience' means in this context since the two senses of 'experience' that are described would call for different measures to gauge continuous improvement. The first sense would call for enhanced training and knowledge to be given to healthcare providers, while the second would require improvement in the terms of employment and the working environment of healthcare providers.

Justification: It prevents ambiguity. It is not clear what 'experience' means here -Is it 'experience' in terms of the length of time and expertise that a healthcare provider has, or is it 'experience' in the sense of their day-to-day feelings/observations pertaining to their work?

Committee resolution: Not adopted. The clause is in order as drafted.

d) Clause 6

Amend Clause 6 (e) by inserting the word "county" after the words "healthcare in all" and by deleting the words "private and faith-based health facilities".

Justification: The responsibility of monitoring the quality of healthcare in private and public facilities should be left to the Authority as assigned under clause 27(f).Assigning this responsibility to the counties creates conflict of interest since the county government are also

providers of similar health services. In addition, it will amount to duplication of regulatory mandate and roles because both the county governments and the Authority will be seeking to monitor the same facilities, which will negatively affect business of the private sector and faith-based facilities. Clause 6(e) assigns county governments the responsibility of monitoring the quality of healthcare in private and faith-based health facilities which is the responsibility of the Quality Health Care and Patient Safety Authority as assigned under clause 27(f).

Committee resolution: Not adopted. The clause is in order as drafted.

e) Clause 10

We propose that the clause be amended to read as follows: "Further to 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 about their health".

Justification

'Further to" clarifies that the Bill complements Section 8 rather than overrides it. The use of the word "Notwithstanding" in Clause 10(a) of the Bill is not the most appropriate, given that it appears to water down Section 8 of the Health Act, which contains important provisions.

f) Clause 11

Clause 11(1)(c) should read as follows: "Every person has the right to access quality healthcare services that are- c)Compliant with quality healthcare standards prescribed under this Act".

Justification: The proposal regarding the phrase Quality of healthcare" articulated above should also apply to Clause 11(c)-the applicable phrase should be "quality healthcare" and not "quality of healthcare". This amendment should also be made to all clauses in the Bill where this change is applicable-e.g. Clauses 17(1),17(3),18(1)(a), and several others. It ensures that there is consistency in the use of terminology.

Committee resolution: Not adopted. The clause is in order as drafted.

g) Clause 18

i. Clause 18(1) (c) can be amended as follows: "18(1) A health facility shall—

(c) adhere to the scope of practice for the healthcare providers employed or contracted health facilities as prescribed by the relevant healthcare regulatory bodies;

Alternatively, (c) Adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as prescribed by the Cabinet Secretary following the recommendation of the relevant healthcare regulatory bodies;

Justification: It is inappropriate for the Cabinet Secretary to prescribe scopes of practice, as this is the exclusive mandate of the respective professional regulatory bodies established under statute.

Clause 18(1)(c) is problematic as it fails to acknowledge the critical role of healthcare regulators, when it comes to scopes of practice. The Cabinet Secretary ought not to prescribe scopes of practice, but simply provide oversight to the relevant regulatory bodies.

Committee resolution: Adopted with amendment. The Director-General for Health ought to perform the role of developing scope of practice as the Director-General is the technical advisor on matters touching on the health sector.

ii. There are two main issues with Clause 18(2):

i)The outsized fine for anon-compliant health facility raises questions as to whether the actual intention in the Bill is to grind such facilities to a halt. The Bill does not seem to have taken into account that health facilities come in all sizes - some fairly modest-and therefore such a fine would sound the death-knell for many facilities.There are undoubtedly some health facilities in existence that really ought not to be running, given the poor quality of services provided. However, KES 50Mn is extremely punitive by any standard, and it is doubtful that exorbitant fines would necessarily cure/deter quality and safety issues, which may have systemic roots.

ii)The reference to a jail term/imprisonment for a health facility is peculiar and cannot be implemented. The Bill must correctly locate and specify the person who should be held responsible for the failures of quality care and patient safety. Again, such failures may be due to systemic issues outside the control of health facilities, and the sponsor of the Bill ought to bear this in mind.

Committee resolution: Adopted with amendment.The proposed penalty was too punitive and yet most of the issues may be systemic in nature.

h) Clause 20

Clause 20(2) could be improved by expressly permitting the Director-General to consult with other persons/bodies in the making of guidelines.

Justification: It ensures that the guidelines are informed by the knowledge and experience of other persons/ bodies and other relevant stakeholders.

Committee resolution: Not adopted. The clause is in order as drafted.

i) Clause 21

Several concerns arise with Clause 21(2) as follows:

i)Is the health facility expected to audit its own safety through an internal audit?

ii)What assures the independence or impartiality of an audit emanating from the health facility itself?

iii)Why are there no provisions for an independent entity to audit the health facility?

iv)A requirement for an independent audit would certainly have financial implications for the health facility. Who/what would the most suitable party to absorb this cost?

v)Given the varying sizes/types of health facilities, some may need to pay more funds to be audited than others. How can the Bill put in place measures to ensure that there are no corrupt dealings that would influence the making of a favorable report when the situation on the ground calls for sanctions including closure of the health facility?

In view of all these concerns, the most ethical route is for the Bill to provide for either:

a)the envisaged Quality Healthcare and Patient Safety Authority ("the Authority") to undertake this role--;or,

b) require health facilities to pick an independent auditor from a pre-approved/prequalified list (these measures, however, may also have their cons-including the possibility of a health facility compromising any such entities).

In the event the Authority is to carry out the Audit, funds should be budgeted for this task by national government.

Justification: To preserve the integrity of audits, the most ethical and effective approach is to vest responsibility either in the Authority or in independent auditor. This will ensure impartiality, accountability and fairness.

Committee resolution: Not adopted. The clause is in order as drafted.

j) Clause 22

The LSK proposes as follows: "The Cabinet Secretary, in consultation with relevant healthcare and patient safety bodies, shall develop a quality improvement framework for health facilities, which shall...".

Justification: There is a lack of a requirement for the Cabinet Secretary to act in consultation with other bodies or persons. It ensures that the framework is informed by the knowledge and experience of other persons/bodies and other relevant stakeholders.

Committee resolution: Not adopted. The clause is in order as drafted.

k) Clause 24

LSK proposed that since omissions cannot strictly be 'committed', the word 'committed' should be deleted in clause 24(1).

Justification: Deleting the word committed eliminates potential interpretive confusion, enhances clarity and ensures the clause accurately reflects the legal intent to cover all forms of liability arising from acts or omissions in the course of providing health services.

Committee resolution: Not adopted. The clause is in order as drafted.

l) Clause 27

LSK proposed the deletion of "as" that is between the words be and necessary in clause 27(o).

Justification: There is some repetition of the word 'as'. This amendment enhances readability and ensures consistency with standard drafting practice.

Committee resolution: Noted. The minor error to be edited.

m) Clause 29

The composition of the Board of Directors of the Authority in Clause 29 should be reconsidered, so as to include a diversity of appointees, recommended by healthcare stakeholders who are outside of the National Government's Executive arm. Healthcare professional bodies, healthcare stakeholders, and patient safety representatives must be included in the Board of Directors. Proposed the amendment of Clause 29 (g) by inserting the words "private and faith- based" after the words "to represent" and by inserting the words "nominated by the forum of private and faith-based healthcare providers".

Justification: Private and faith-based healthcare service providers play a critical role in health care service delivery in Kenya; therefore, they should be represented in the Board of the Authority. The person representing the public should have knowledge and experience in healthcare management or quality improvement. This will ensure there is value addition to the representation in the Board. This clause concerns the composition of the Board of Directors of the Authority. Clause 29 as drafted is overwhelmingly populated by appointees of the National Government's Executive arm. The Cabinet Secretary is given undue latitude to appoint persons to the Board without the involvement of healthcare stakeholders, who are better placed to recommend their own representatives to the Board. This clause is

exclusionary, and increases the perception (rightly so), of the Board being a preserve of political appointees. Further, the clause as drafted fails to give space to other healthcare professional bodies and healthcare stakeholders, as well as patient representatives, who have expertise and broad perspectives that would enrich the Board. Clause 29 (g) provides generally for representation of health care providers, which includes individuals or organizations. The clause does not provide for representation of private and faith-based healthcare providers, who are leading service providers in the country Clause 29 (g) provides for appointment of a person to represent the public. This leaves room for the Cabinet Secretary to appoint any person irrespective of their expertise on health-related matters.

Committee resolution: Adopted with amendment. This will ensure that the interests of statutory regulatory bodies are well take into account by the proposed Authority. The clause already makes provision for the representation of healthcare providers.

n) Clause 30

Clause 30(1) must raise the bar regarding the educational qualifications of the Chairperson of the Board of Directors of the Authority, by at the very least, requiring a minimum of a Master's degree in a relevant area (in addition to the other requirements listed).

Justification: This clause concerns the qualifications and experience of the Chairperson of the Board of Directors of the Authority. Clause 30(1),by pegging the educational level of the Chairperson of the Board of Directors of the Authority to a Bachelor's degree, is setting the bar rather low. Given that the Board will be required to set standards for other healthcare professionals to follow(many trained to high levels), it surely should require a Chairperson with credible post-graduate qualifications of at least a Master's level, in addition to the years of working experience required. Pegging the minimum educational qualification of the Chairperson at a Bachelor's degree risks undermining the credibility and effectiveness of the Authority's governance framework. This higher standard strengthens the Authority's legitimacy, enhances stakeholder confidence, and aligns the leadership of the Board with the level of responsibility it carries in shaping national healthcare standards and safeguarding public health.

Committee resolution: Not adopted. The clause is in order as drafted as a Bachelor's Degree is sufficient in the circumstances.

o) Clause 40

LSK proposed to amend the word "act" to "acts" in cause 40(2).

Justification: This is more a typographical rather than substantive error-to add the letter to the word 'act', so that it is in plural form. Retaining the singular act" could be misinterpreted to mean that liability only attaches to one unlawful or criminal act, leaving a loophole where multiple unlawful or criminal acts might not be captured. Changing it to "acts" ensures comprehensive coverage and closes any potential interpretive gap.

Committee resolution: Noted. The minor error will be edited.

p) Clause 42

LSK proposed to amend clause 42(2) to: "The Cabinet Secretary shall in consultation with relevant experts and healthcare bodies, prescribe the requirements for-
a) health facilities
b) ambulances

c) aircraft designated for use in medical evacuation and transport;
d) medical camps; and
e) such other health facility as may be prescribed by the Cabinet Secretary."

Justification: It ensures that policies, standards and guidelines are informed by the knowledge and experience of regulatory bodies and other relevant stakeholders.

Committee resolution: Not adopted. The clause is in order as drafted.

i. Amendment of clause 42(6) to: "(6) The Cabinet Secretary shall in consultation with relevant experts and healthcare bodies develop standards for the construction, operation and decommissioning of a health facility."

Justification: It ensures that policies, standards and guidelines are informed by the knowledge and experience of regulatory bodies and other relevant stakeholders.

Committee resolution: Not adopted. The clause is in order as drafted.

q) Clause 46

Clause 46(2) must make it mandatory for the Authority to communicate a decision to suspend the registration of a facility, so as to give the facility sufficient opportunity to appeal if it so wishes.

Justification: Our proposal aligns with Article 47 of the Constitution and Sections 3&4 of the Fair Administrative Action Act,2015,which require adequate notice, reasons for decisions and an adequate opportunity to challenge adverse decisions. The current drafting risks violating these standards and exposing the Authority's decisions to judicial review for procedural unfairness. Clause 46(3) must clarify its timelines to give a health facility sufficient time to lodge an appeal if it so wishes. Therefore, the clock for a facility facing the threat of suspension should only start ticking from the date of service of the notification from the Authority, and not "from the day of the notification under subsection (2)"-this is confusing, unclear, and is bound to be a litigation question in future if not amended. Clause 42(2) concerns a non-mandatory (i.e.optional) notification by the Authority to a health facility whose registration it intends to suspend, while Clause 43(3) concerns the health facility's right of appeal to a Tribunal upon receipt of such notice from the Authority. The provisions and timelines set out in Clause 46(2) and 46(3)do not give a health facility sufficient notice or opportunity to challenge/appeal a decision by the Authority to suspend a certificate of registration. The questions arising therefrom are:

i) If the Authority may (in Clause 46(2),notify a person/health facility (an optional act),how then can an affected person lodge an appeal in the event they are not notified by the Authority? The affected person cannot appeal that which they know not about.

ii) If the Authority may (in Clause 46(3),notify a person "twenty-one days before the date of the intended suspension", yet the affected person is also to lodge an appeal "within twenty-one days from the day of the notification under subsection (2)", it is surely clear that for the affected person/health facility, their twenty-one days run out just as soon as/on the day the intended suspension kicks in. There is therefore, in reality, no twenty-one-day period for the affected party to lodge an appeal, but a much shorter time-if at all-since they may not even have been notified of the intention to suspend in the first place.

If the intention of Clause 46(3)is for the twenty-on day period to run from the date of service of the notice(rather than "from the date of the notification" as it currently states),it should make this clear by appropriate re-drafting of the subsections.

Committee resolution: Not adopted. The clause is in order as drafted in light of the circumstances.

r) Clause 47

i. Proposed that the provision be made mandatory by replacing the word 'may' with "shall" in clause 47(2).

Justification: Clause 47(2) concerns a non-mandatory(i.e. optional) notification by the Authority to a health facility whose registration it intends to revoke, while Clause 47(3) concerns the health facility's right of appeal to a Tribunal upon receipt of such notice from the Authority. The LSK proposal aligns with Article 47 of the Constitution and Sections 3&4 of the Fair Administrative Action Act,2015,which require adequate notice, reasons for decisions and an adequate opportunity to challenge adverse decisions. The current drafting risks violating these standards and exposing the Authority's decisions to judicial review for procedural unfairness.

Committee resolution: Not adopted. The clause is in order as drafted.

ii. Proposed that the word 'licence' should be deleted and replaced with 'certificate of registration ' in clause 47(3) for consistency.

Justification: Correcting the error ensures consistency, legal certainty, and prevents interpretive confusion. An additional issue in Clause 47(3) concerns the use of the word "licence" rather than "certificate of registration" in Clause 47(3), which appears to be an error.

Committee resolution: Not adopted. The clause is in order as drafted.

s) Clause 54

The amendments proposed for Clause 46(2)and(3);and Clause 47(2) and (3) above, also apply to Clauses 54(2) and (4).Further the erroneous reference in Clause 54(4)to "notification under subsection (1)", should be corrected to read "notification under subsection (2)".

Justification: Clause 54(2) concerns a non-mandatory(i.e. optional) notification by the Authority to a health facility whose licence it intends to suspend, while Clause 54(4) concerns the health facility's right of appeal to a Tribunal upon receipt of such notice from the Authority.

Committee resolution: Not adopted. The clause is in order as drafted.

t) Clause 55

Clause 55(4) should include an obligation on the Authority to render its decision concerning revocation within a given time-frame-Fourteen, or Twenty-One Days, seems to be a reasonable time for a facility to receive a written decision from the Authority

Justification: Clause 55(4) concerns the discretion of the Authority to revoke a licence after receiving reasons from a health facility. The issue of timelines arises in Clause 55(4),where "the Authority shall, after considering the reasons, decide on whether or not to revoke the

licence". Setting a specific timeline provides certainty. It strikes a balance between allowing the Authority sufficient time to fairly consider the reasons advanced by the facility and ensuring that the facility receives a timely written decision.

Committee resolution: Not adopted. The clause is in order as drafted.

u) Clause 57 to 64

Proposed the amendment of Clause 57 to 64 by deleting the word "Authority" and substituting therefor the words "Kenya Accreditation Service", save for any section that may specifically be referring to the reasonability of the Authority to issue licenses under the Bill.
Justification: Clause 57 to 64 provides for accreditation of health facilities by the Quality Health Care and Patient Safety Authority, which is conflict of mandates and roles because the Authority's mandate is to regulate the healthcare facilities and not accredit the facilities. In addition, the clauses usurp the function and mandate of the Kenya Accreditation Service (KENAS),which is the government body responsible for accreditation services for standards and quality management. Licensing of healthcare facilities should be separated from accreditation. The conventional practice is that the function of accreditation is carried out by an independent body from the one issuing licenses. The Authority should focus on licensing and regulating the healthcare facilities. The Kenya Accreditation Service (KENAS), is the government body responsible for accreditation services for standards and quality management. By separating the licensing and accreditation roles and having them being carried out by different bodies, the Bill will enhance accountability and improvement of quality services.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

v) Clause 63

The amendments proposed for Clauses 46(2) & (3); 47(2) & (3);and 54(2) & (4), also apply to Clauses 63(2)and (4). The applicable date from which any time should begin to run (where a health facility is facing suspension of accreditation),should be from the date of service of the notification of suspension. The typographical error in Clause 63(2) where "the",(between 'suspend' and 'accreditation'), has been typed as "he", should also be corrected. Subclause (4) be amended to "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."

Justification: The provisions and timelines set out in Clause 63(2) and 63(4)do not give a health facility sufficient notice or opportunity to challenge/appeal a decision by the Authority to suspend its accreditation-firstly, because it is couched as non-mandatory(i.e. optional) for the Authority to notify a facility, and secondly, because the timelines given overlap/expire before a health facility has any meaningful opportunity to respond. The same issues pointed out above concerning Clauses 46(2) & (3);47(2) & (3); and 54(2)& (4) are replicated here, but with one difference-Clause 63(4) clarifies that the notification at issue is The "notification of suspension", and not just a general "notification. This clarification cannot be assumed to apply to previous sections pointed out here. However, that addition still does not give a health facility sufficient notice (time-wise) to respond, since, as pointed out earlier, the time given to a health facility for response may run out even before a health facility has been notified (if at all). Questions arise as to whether the applicable date is "the day of the notification of suspension" (as currently stated in the Bill),or; "the date of service of the notification of suspension"(which the Bill fails to frame as such). The latter ought to be the applicable/preferable).

Committee resolution: Not adopted. The clause is in order as drafted.

w) **Clause 75**

The phrase "duly qualified" is rather vague and non-specific; Recommends that the Regulations under this Act sets out at the very least, the minimum qualifications and experience expected of an inspector of the Authority.

Justification: Such a requirement will aid in enhancing the Authority's transparency, as well as ensuring a high level of accountability for the inspectors.

Committee resolution: Not adopted. The clause is in order as drafted.

x) **Clause 83**

The proposal in Clause 83(2) to subsume what should have been a separate Dispute Resolution Tribunal into the proposed Healthcare Tribunal, is likely to leave persons affected by disputes arising from social health insurance without specialist expertise and determinations of their complaints. Further, complaints arising from the Social Health Insurance Act, 2023, may be numerous, and therefore, dominate other types of matters brought before the Healthcare Tribunal at the expense of complaints that touch on quality healthcare and patient safety.

Clause 83(2) should be carefully reconsidered, and the final Bill must reflect a decision that best serves wananchi without their having to suffer undue delays, as well as one that bears in mind the need for prudent use of the nation's already-strained finances.

Justification: Merging the functions of the proposed Healthcare Tribunal with the Dispute Resolution Tribunal established under the Social Health Insurance Act,2023, risks undermining the effectiveness and efficiency of both bodies. This clause generally concerns the proposed 'Healthcare Tribunal'. It is inadvisable to mix the functions and mandate of the Dispute Resolution Tribunal under the Social Health Insurance Act, 2023,with what is clearly a mandate (Quality Health and Patient Safety),that requires a different set of knowledge, skills and approach. The expertise required to fulfill the mandate of the Bill is vastly different from potential disputes that could arise under the Social Health Insurance Act, which disputes are likely to concern matters such as levels of insurance coverage, refusals to approve treatment, etc.

Committee resolution: Adopted with amendment. The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

Amend Clause 83 to provide that one member shall be an Advocate of the High Court of Kenya.

Justification: Given that the Tribunal exercises quasi-judicial functions, requiring that at least one member of the Tribunal be an Advocate of the High Court of Kenya, it ensures that the Tribunal's deliberations and decisions benefit from legal expertise, particularly in the interpretation and application of the law.

Committee resolution: Not Adopted. The clause already makes provision for three advocates.

y) **Clause 84**

Clause 84 must confine the Tribunal to quality healthcare and patient safety disputes that broadly involve healthcare facilities, and not exceed its anticipated role and powers to veer into the territory of healthcare regulatory bodies and the professionals they oversee (including that of the Kenya Health Professions Oversight Authority).Even where a healthcare professional is implicated in an unlawful act, and the Authority's inspector say, temporarily suspends the operations of a health facility under Clause 79,the inspector should be at liberty to refer the healthcare professional to his/her relevant regulatory body for disciplinary action under Clause 79(1)(b).

Justification-The Clause as currently drafted grants the Tribunal an excessively broad jurisdiction that overlaps with the mandates of healthcare regulatory bodies, thereby undermining their statutory roles and professional expertise. The Tribunal's jurisdiction should be confined to disputes on quality healthcare and patient safety within health facilities, leaving professional regulation to the respective regulators. Further, to safeguard efficiency and justice, the Tribunal should be required to hear and determine matters within ninety days of filing and where delays occur, furnish written reasons and a clear time-frame for determination. This ensures accountability, timeliness, and alignment with constitutional principles of good governance. The excessively wide jurisdiction Clause 84(3) is bound to cast aside the role of healthcare regulatory bodies in providing oversight, and disciplinary measures, over their professionals. The composition proposed of the Healthcare Tribunal as set out in Clause 83 cannot, even with the best of intentions, match or supersede the expertise found in healthcare regulatory bodies, which have clearly-defined statutory roles.

Committee resolution: Adopted with amendment. The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

Proposed amendments to Clause 84(6)(a) and an additional 84(6)(b) as follows:
"6(a) "The Tribunal shall hear and determine matters referred to it expeditiously, and shall endeavour to do so within ninety days of the filing of the matter."
(b)Where a matter remains undetermined after ninety days, the Tribunal shall furnish the parties with written reasons for the delay, and a time-frame within which the matter shall be determined.

Justification: A single Tribunal is not capable of resolving such a wide array of potential disputes, with such a diverse array of players--healthcare facilities, providers, patients, etc.--,and numerous health professional cadres, as is being granted by its jurisdiction. There ought to be a requirement that the Tribunal hear and determine matters within a specific time-frame from the date the matter is filed with the Tribunal.

Committee resolution: Not adopted. The clause is in order as drafted, the timelines will be set out in subsidiary legislation.

z) **Clause 93**

Amend Clause 93 (2)(i)) by deleting the word "ambulances services" and substituting therefor the words "emergency medical services or pre-hospital care"

Justification: Clause 93 provides for to prescribe for ambulances services. However, this is a narrow approach as it only focuses on ambulances, which are part of the wider pre-hospital care or emergency medical services. The appropriate terms are emergency medical services

or pre-hospital care, which are more comprehensive, inclusive and covers with wider spectrum of the services, including ambulance services.

Committee resolution: Not adopted. The clause is in order as drafted as the clause makes provision for both ambulance services and emergency medical treatment.

FIRST SCHEDULE
Amendment of paragraph 1(8) by replacing the word "an" with "a".

Justification: The word 'an' is a typographical error, and should be replaced with 'a'. The current wording is a typographical error that should be corrected to ensure grammatical accuracy, clarity and consistency with standard legislative drafting practice.

Committee resolution: Noted. The minor error will be edited.

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENT

Paragraph 1

The existing definition of 'healthcare provider' and "health facility" as defined in the Health Act should be retained. Although the current definition of health facility' in the Health Act suffices, elements such as morgues, may be incorporated.

a)The re-definition of "healthcare provider" is problematic, unnecessary, and is inferior to the existing definition in the Health Act for the following reason;-

The proposed definition of healthcare provider in the Bill does not distinguish between persons currently regulated by a healthcare professionals' regulatory body (e.g. KMPDC, Nursing Council of Kenya, etc.).,and persons currently not regulated, or at best, are only peripherally regulated (e.g. Herbal medicine practitioners).

b) The proposed re-definition of "healthcare services", it states that healthcare services are "delivered by healthcare professionals". If this is the case, why then not let the Health Act's prevailing/existing definition of "healthcare providers "stand?

i)The Bill employs he word "healthcare professional" in the definition of healthcare services, but ignores Point (i) (b) above -that in Kenya, currently, not all persons providing healthcare services are regulated ,and so not all 'healthcare providers' are health professionals. In other words, a 'healthcare professional' is a healthcare provider, but not all 'healthcare providers' are healthcare professionals.

c)The re-definition of 'health facility' manages to miss out important elements that are currently in the Health Act, even as it expands the definition of a 'health facility'. For instance, going by the proposed (new)definition in the Bill, is a doctor's consulting room a health facility? If so, the removal of the word 'out-patient' from the new definition (while it exists in the current definition in the Health Act), is an anomaly that ought to be rectified.

Further omissions in the proposed definition that are key, include leaving out the phrase "the whole or part of a public or private institution, building or place", Describing a 'health facility' primarily as "an institution" (in the Bill),is also limiting its scope.

Generally: All other 'Consequential Amendments to other Acts' listed in the Second Schedule of the Bill must be re-checked, re- drafted and/or deleted where their effect is to propose the extension of the Authority's or Tribunal's powers into what should be the remit of healthcare

regulatory bodies, and in particular, scopes of work, oversight, and discipline of healthcare professionals.

Justification: The proposed re-definitions are unnecessary and risk creating confusion.

Committee resolution: Adopted with amendment.The definition of the term "healthcare provider" is more comprehensive as it includes a healthcare professional providing healthcare services.

General Comments by the Law Society of Kenya on the Bill

1. The Bill first came to the attention of members of the Law Society of Kenya through an invitation to the LSK from the Ministry of Health to attend a Stakeholder Engagement Forum on the Bill. Subsequently, members of the LSK Medico-Legal Committee who attended the Forum on 19th June 2025 at Weston Hotel, Nairobi, prepared and submitted a Report to LSK, noting several concerns pertaining to the Bill.
2. At the time the Forum took place, the Bill had yet to be submitted to the National Assembly and was still a legislative proposal. In its Report, the LSK stated that it was premature for LSK members to comment, hoping the Forum's discussions would prompt the Ministry of Health to consult healthcare stakeholders and make necessary amendments before sending the Bill to the National Assembly.
3. The LSK acknowledged that the Ministry of Health indeed, took into consideration some of the concerns raised at the Forum (including by the LSK) and made the following amendments to the Bill:
    i. The Bill submitted to the National Assembly spared the HIV and AIDS Tribunal which was previously slated for disestablishment. The Dispute Resolution Tribunal established under the Social Health Insurance Act is however still to be done away with (see Clause 83 of the Bill) and be succeeded by a proposed Health Care Tribunal; and
    ii. The Bill now gives the Director-General for Health the power to develop and publish clinical guidelines, rather than the Cabinet Secretary. However, this would neither cure the objections previously raised by healthcare stakeholders in the Forum concerning misplaced expertise nor cure potential conflicts of interest on the part of the Director-General. Still, some clauses in the Bill make reference to the Cabinet Secretary prescribing scopes of practice (e.g. Clause 18(1)(c). This was one of the objections to the Bill that was raised by attendees at the Forum and articulated in our Report. The LSK has reviewed the published Bill and note that while some earlier concerns were addressed, several provisions remain problematic.
4. It is important to note that for the Bill to meet its objectives, it requires adequate resources in terms of human, infrastructural, financial and capacity-building among others. If the Bill is enacted, the National and County Governments must be prepared to commit sufficient resources to see to it that the Bill's aims are not frustrated.

Committee resolution: The Committee noted the general comments.

36. **KENYA ACCREDITATION SERVICE (KENAS)**

The Kenya Accreditation Service (KENAS) submitted as follows;

a) **Clause 2**

i. Substitute the phrase "accreditation for quality of healthcare" with "certification for quality healthcare".

Justification: The nature of accreditation defined in the clause and assigned to the Authority under Section 28(f) in the Bill is third party attestation of competence, to international standards for healthcare facilities. This is a mandate allocated to National Accreditation Bodies (in Kenya, the Kenya Accreditation Service) under ISO/IEC 17000 Standards series more specifically ISO/IEC 17011:2012 which is domesticated in Kenya through the Kenya Accreditation Service Act CAP 497A Laws of Kenya. The Quality Healthcare and Patient Safety Authority may therefore be a certifier certifying quality healthcare to ISO 7101:2023 (Management systems for healthcare organizations) or a locally established standard but not an accreditation body under ISO/IEC 17000 Standards series. The change will ensure that the Bill does not conflict with the Kenya accreditation Service Act and that there is coherence with the established principles on structuring of national quality infrastructure institutions.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

ii. Introduce a definition of the term accreditation reading as follows: "Accreditation" means an attestation by the Service established under the Kenya accreditation Service Act that a medical laboratory is competent to carry out specific conformity assessment tasks

Justification: Defines the word accreditation as shall be used under the proposed section 46(cc), 61(e).
Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

b) Clause 19

Introduce a new subsection after subsection (1)(c) to read as follows: "provide diagnostic services or perform diagnostic procedures using equipment calibrated by calibration laboratory accredited under the relevant law."

Justification: The use of non-calibrated diagnostic equipment is the panacea of misdiagnosis in healthcare. When diagnostic tools yield uncertain or inaccurate results, the entire continuum of care is compromised, leading to wrong treatment, delayed interventions, wastage of resources, and in the worst cases, preventable morbidity and mortality. Certainty in diagnosis outcomes, on the other hand, promotes certainty in treatment, safeguarding patient safety and improving health outcomes. Calibration of diagnostic equipment by accredited laboratories ensures that diagnostic equipment produces accurate and reliable results. This reduces the risks of misdiagnosis and guarantees that clinical decisions are based on trustworthy data.

Global health frameworks, including those advocated by WHO, emphasize the reliability of diagnostic results as fundamental to safe healthcare. Accreditation of calibration laboratories according to international standards such as ISO/IEC 17025:2017 aligns Kenya's healthcare quality requirements with international norms. The provision anchors calibration obligations within the law, ensuring that all healthcare facilities uniformly adhere to the same standards. This removes ambiguity and strengthens regulatory oversight. Embedding accreditation into the law assures patients and stakeholders that diagnostic outcomes are scientifically valid, thereby enhancing public trust in Kenya's healthcare system. The requirement leverages existing legal and institutional frameworks i.e. the Kenya Accreditation Service Act, CAP.

496A, promoting synergy between healthcare regulation and the national quality infrastructure. Proper calibration averts unnecessary repeat testing, costly malpractice claims, and inefficiencies caused by faulty equipment. Over time, it reduces systemic risks and healthcare expenditure.

Committee resolution: Not adopted. The clause is in order as drafted.

c) **Clause 23**

Substitute the word *accreditation* with *certification.*

Justification: The nature of accreditation defined in the clause and assigned to the Authority under Section 28(f) in the Bill is third party attestation of competence, to international standards for healthcare facilities. This is a mandate allocated to National Accreditation Bodies (in Kenya, the Kenya Accreditation Service) under ISO/IEC 17000 Standards series more specifically ISO/IEC 17011:2012 which is domesticated in Kenya through the Kenya Accreditation Service Act CAP 497A Laws of Kenya. The Quality Healthcare and Patient Safety Authority may therefore be a certifier certifying quality healthcare to ISO 7101:2023 (Management systems for healthcare organizations) or a locally established standard but not an accreditation body under ISO/IEC 17000 Standards series. The change will ensure that the Bill does not conflict with the Kenya accreditation Service Act and that there is coherence with the established principles on structuring of national quality infrastructure institutions.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

d) **Clause 28**

Substitute the word *accreditation* with *certification.*

Justification: The nature of accreditation defined in the clause and assigned to the Authority under Section 28(f) in the Bill is third party attestation of competence, to international standards for healthcare facilities. This is a mandate allocated to National Accreditation Bodies (in Kenya, the Kenya Accreditation Service) under ISO/IEC 17000 Standards series more specifically ISO/IEC 17011:2012 which is domesticated in Kenya through the Kenya Accreditation Service Act CAP 497A Laws of Kenya. The Quality Healthcare and Patient Safety Authority may therefore be a certifier certifying quality healthcare to ISO 7101:2023 (Management systems for healthcare organizations) or a locally established standard but not an accreditation body under ISO/IEC 17000 Standards series. The change will ensure that the Bill does not conflict with the Kenya accreditation Service Act and that there is coherence with the established principles on structuring of national quality infrastructure institutions.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

Part IV

In clauses 58, 59, 60,61,62,63,64,65 and 66, substitute the word *accreditation* with *certification.*

Justification: The nature of accreditation defined in the clause and assigned to the Authority under Section 28(f) in the Bill is third party attestation of competence, to international standards for healthcare facilities. This is a mandate allocated to National Accreditation Bodies (in Kenya, the Kenya Accreditation Service) under ISO/IEC 17000 Standards series

more specifically ISO/IEC 17011:2012 which is domesticated in Kenya through the Kenya Accreditation Service Act CAP 497A Laws of Kenya. The Quality Healthcare and Patient Safety Authority may therefore be a certifier certifying quality healthcare to ISO 7101:2023 (Management systems for healthcare organizations) or a locally established standard but not an accreditation body under ISO/IEC 17000 Standards series. The change will ensure that the Bill does not conflict with the Kenya accreditation Service Act and that there is coherence with the established principles on structuring of national quality infrastructure institutions.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

e) **Clause 46**

Introduce a new paragraph after paragraph (c) worded as follows; "(cc) evidence that the health facility laboratory and diagnostic imaging facilities are accredited under the Kenya Accreditation Service Act".

Justification: Section 46 of the Quality Healthcare and Patient Safety Bill 2025 provides criteria for registration of healthcare facilities. However, the current provisions do not explicitly include medical laboratories and diagnostic imaging facilities, despite their central role in clinical decision-making. Excluding these facilities from registration requirements creates a regulatory gap, exposing patients to the risk of inaccurate diagnostics and undermining the quality of healthcare delivery. To close this gap, it is necessary to expressly include them as part of the criteria for facility registration. Laboratories and imaging facilities provide essential diagnostic information that directly influences treatment decisions. Omitting them from registration requirements may allow substandard or unregulated facilities to operate, weakening the integrity of the health system. Their inclusion ensures that all critical aspects of patient care are subject to the same regulatory scrutiny as other healthcare services.

More than 70% of clinical diagnoses rely on laboratory or imaging results. Inaccurate or unreliable outputs can lead to misdiagnosis, delayed interventions, and patient harm. Requiring accredited laboratories and imaging facilities as part of facility registration ensures that diagnostic services meet rigorous quality and safety standards. Accreditation under the Kenya Accreditation Service Act, 2019 verifies that a laboratory or imaging facility is competent and compliant with international standards such as ISO 15189 for medical laboratories and ISO/IEC 17025 for calibration and testing laboratories. Making accreditation part of the registration requirement ensures that only competent facilities are licensed to operate. Patients and practitioners must trust the results produced by diagnostic facilities. Accreditation offers that assurance by confirming the reliability and consistency of test results, thereby reinforcing public confidence in registered health facilities.

Jurisdictions worldwide, including within the African region, require diagnostic facilities to demonstrate accreditation as a precondition for licensing. Inclusion of this requirement ensures Kenya keeps pace with global health regulation standards and enhances international recognition of its health services. Linking health facility registration to the Kenya Accreditation Service strengthens coordination between healthcare regulation and the national quality infrastructure, ensuring efficiency, standardization, and international credibility.

The inclusion of medical laboratories and diagnostic imaging facilities in Section 46 as a mandatory requirement for registration is critical for closing existing regulatory gaps, safeguarding patient safety, and ensuring consistency in healthcare standards. Requiring

evidence of accreditation further elevates the quality threshold, aligning Kenya's healthcare system with international best practice and promoting sustainable, reliable, and trusted healthcare delivery. For medical laboratories, this accreditation is mandatory to ascertain compliance to ISO 15189 to ensure global alignment; addresses high-risk areas; strengthens patient safety; preserve Kenya's international credibility; and assist the authority carry out its regulatory mandate by covering existing gaps.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

f) **Clause 56**

Introduce a new subsection after subsection (1)(a) to read as follows:(aa) its medical laboratory is suspended or withdrawn from accreditation under the Kenya Accreditation Service Act.

Justification: This will facilitate a one government approach in ensuring quality in healthcare wherein sanctions for noncompliance to quality requirements will attract similar consequences.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

g) **Clause 61**

Amend clause 61(e) to read as follows; "(e) accreditation of medical laboratory and diagnostic imaging facilities."

Justification: Accreditation is the already existing methodology of determining that laboratories and imaging facilities comply with standards. (Further justification aligned with clause 46 above.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

General Comments by KENAS on the Bill
KENAS submitted that its proposals align the Bill with international best practices.

Committee resolution: The Committee noted the general comment.

37. **KENYA HEALTHCARE FEDERATION (KHF)**
The Kenya Healthcare Federation (KHF) submitted as follows;

a) **Clause 2**

Consider including the following new definition: "Patient safety" means prevention of harm to patients during the process of healthcare delivery. It focuses on minimizing risks, errors, and adverse events that could result from medical care rather than from the patient's underlying condition. It includes but not limited to ensuring accurate diagnoses and treatments, reducing medication errors, preventing infections and surgical complications, creating systems for reporting and learning from mistakes.

Justification: Provides clarity within the meaning of the Act. Clear interpretation of terms provides precision and consistency avoiding ambiguity and gives guidance for implementation of laws.

Committee resolution: Not adopted. The term is used in its ordinary sense.

b) Clause 18

Consider the following inclusion: "(cc) The Cabinet Secretary shall ensure that the scope of practice for all healthcare cadres employed or contracted in health facilities are developed, published, and reviewed at least every three years."

Justification: This will provide practical flexibility and avoids penalizing Health Facilities. Further in instances where the scope of practice is not yet published, facilities may continue the existing duties for these cadres for up to two years as the relevant regulatory authority finalizes and gazettes an official scope.

Committee resolution: Not adopted. The clause amended to provided that the Director-General for Health ought to perform the role of developing scope of practice as the Director-General is the technical advisor on matters touching on the health sector

c) Clause 20

Amend clause 20(2) to: "(2) The Director-General, develop and publish clinical guidelines at least every three years or in response to major public health developments, and shall maintain a publicly accessible repository of current guidelines."

Justification: The stipulation by the Director-General to develop and publish clinical guidelines from time to time is ambiguous and a clear definite time should be set to create consistency in applicable.

Committee resolution: Not adopted. The clause is in order as drafted as clinical guidelines will be published from time to time.

d) Clause 21

Consider the following inclusion: "e. Establish and implement Clinical Risk Management measures as prescribed by the Cabinet Secretary reviewed at least every three years".

Justification: Kenya lacks a harmonized IPC guideline framework; basing requirements on evidence-aligned national standards improves clarity and feasibility. Infection Prevention Surveillance and Control measures is just an aspect of Clinical Risk Management and therefore narrows the focus Risk Management in Patient Safety.

Committee resolution: Not adopted. This is already factored in the clause.

e) Clause 22

Amend clause 23(4) as follows: "(4) Compliance with quality improvement standards shall inform accreditation and performance assessment. Access to the Social Health Insurance Fund shall be subject to a transparent, phased framework with due process, allowing facilities to align progressively with quality improvement benchmarks."

Consider the following inclusion: "(4a) The Authority shall collaborate with existing bodies such as Kenya Accreditation Service for purposes of ascertaining technical competence.

Justification: Compliance should be deemed as contribution but it should not be the sole basis for SHA accreditation.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare as contemplated in the social health insurance law.

f) Clause 23

Clause 23 (a) is amended as follows: :(a) verify qualifications and active licensure, where such licensure exists, from the relevant regulatory body. For healthcare providers not yet formally licensed, county governments shall maintain verified competency records and submit them annually to the Authority for review."

Justification: Given the expanded definition of healthcare providers in in Part I (2) of this bill that includes up to community health workers, options should be provided for health workers without regulatory bodies.

Committee resolution: Adopted with amendment. The clause amended to specify that the training is for the employees of the owner of a health facility.

g) Clause 24

Clause 24(1) is amended as follows: "1)Every health facility shall maintain professional indemnity cover appropriate to its level of risk, as prescribed by the Cabinet Secretary in consultation with sector stakeholders"

Consider the following inclusion ":24(2)(c) The Authority shall phase in individual professional indemnity for healthcare providers based on cadre, risk exposure, and ability to pay, and may coordinate subsidized schemes.".

Justification: This is the first-time indemnity is made mandatory. While globally aligned, it could raise compliance costs and lead to risk-averse behavior or doctor attrition without support mechanisms. Mandatory professional indemnity should be phased in with guidance from respective regulators and tied to facility size and service complexity.

Committee resolution: Not adopted. The clause is in order as drafted and proposed issues could be handled in subsidiary legislation.

h) Clause 27

Amend clause 27 as follows:

(a) Delete paragraph (a) and substitute therefor the following new paragraph: "regulate the development of health"
(b) Delate paragraph (b) and substitute therefor the following new paragraph: "register health facilities"
(c) Under paragraph (e),add "or allow for sub contraction of independent entities, whereas the authority provides oversight".

Justification: The functions of the Authority should be streamlined to give sufficient attention to quality of care and patient safety while avoiding duplication with councils. Inspection, accreditation, and policy oversight should involve co-regulation with councils under a statutory Joint Regulatory Coordination Committee. Accreditation should be done by an independent body such as KENAS. An equalization framework needs to be

established by the authority for recognition of other certification frameworks and international standards aligned to KQMH framework.

Committee resolution: Not adopted. The clause is in order as drafted. The Authority will accredit for purposes of quality healthcare.

i) Clause 29

Clause 29(1)(g) amended to (g) An individual appointed by the cabinet Secretary not being public officers, nominated by:

(i) Private sector
(ii) Patient's association in Kenya;
(iii) Consortium of health care providers.

Justification: The inclusion broadens the level of representation and enhances more accountability and informed decision making as well as balanced interests. Further the stakeholder representation should be ratified by their respective groups, not merely nominated and appointed by the Cabinet Secretary. The appointments should be subject to public vetting or parliamentary approval for transparency.

Committee resolution: Not adopted. The clause is in order as drafted. Healthcare providers and the public which includes patients are already provided for.

j) Clause 49

Delete clause 49(f).

Justification: This provision may not apply to all medical facilities. Clause 49 outlines crucial mandatory documents that are required during application of a licence. However, the requirement of (g) should not be mandatory. Prescribe the medical facilities that be applicable with specifics to their level of operations.

Committee resolution: Not adopted. The clause is in order as drafted. Conditions for licensing are necessary for uniformity.

k) Clause 56, 57 and 58

Delete clause 56, 57 and 58.

Justification: Registration, Licensing, accreditation and practice oversight of health facilities is rightly placed away from the professional regulatory bodies which has always brought fractured oversight of quality of care in the facilities.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

l) Clause 62

Amend clause 62 by inserting a new sub-clause (2) "(2) Once the health facility has fulfilled all reaccreditation application requirements, the authority shall issue a provisional accreditation for another 90 days".

Justification: This will be a recourse for health facilities in instances where there is delay from the Authority in issuance of the accreditation or inaction due to technical hitches.

Committee resolution: Not adopted. The clauses is in order as drafted. There is no need for a provisional accreditation.

m) Clause 67

Amend clause 67(2)(b) to: (b) used to determine eligibility for transparent, performance-based incentives as defined in regulations, provided that such incentives are structured to avoid penalizing low-resource or underserved facilities and include a clear appeals process.

Justification: Safeguards against misuse or politicization, promotes equity across public and private facilities, enforces regulatory clarity, and minimizes the risk of manipulation.

Committee resolution: Not adopted. The clause is in order as drafted. The details of incentives will be handled in subsidiary legislation.

n) Clause 79

Amended clause 79(1)(a) as follows: "a)Order the temporary suspension of the healthcare service or health facility only in cases of imminent risk to patient safety or serious legal violation, and shall issue a written suspension notice within 24 hours outlining reasons and appeal options, with due regard to continuity of patient care".

Justification: Prevents arbitrary or disproportionate action; protects business continuity and patient safety; aligns with Article 47 of the Constitution on fair administrative action.

Committee resolution: Not adopted. The clauses are in order as drafted. Immediate closure is necessary where there is grave risk for injury or damage to patients.

o) Clause 80

- Amend clause 80(1)(a) by inserting the following new paragraph immediately after paragraph (a) —aa) Subject to (a) where the objection is valid, the facility shall be given at least 14 days to be heard or provide further documentation in support of the objection and an internal review process instituted to necessitate the proportionality of the proposed action.

- Insert the following new paragraph under clause 80(2) as follows: (c)A review by a designated quality assurance panel within the Authority, which includes representation from professional councils and private sector stakeholders, has confirmed the necessity and proportionality of the proposed action.

Justification: Prevents arbitrary closure or penalties. Establishes clear, fair, reviewable procedure especially important for private sector viability and legal compliance. Ensures decisions are proportionate and include technical and sectoral input; prevents arbitrary or overly punitive actions; safeguards professional autonomy. The right to be heard should be applied on a case by case basis and shouldn't be abused in instances where patients right have been outrightly been prejudiced.

Committee resolution: Not adopted. The clauses are in order as drafted. Immediate closure is necessary where there is grave risk for injury or damage to patients.

General Comments on the Bill by Kenya Healthcare Federation (KHF)

1. The term "patient safety" is not defined in the bill. The interpretation of patient safety should be premised in the bill in order to assure the attainment of the objective of the bill

as set out in clause 3 which is "to guarantee patient rights and patient safety" and equally set parameters that ascertain safety of patients in medical institutions.

2. The proposed Quality Health Care and Patient Safety Authority is granted extensive powers across registration, licensing, inspection, enforcement, accreditation, penalty imposition, and linkage to Social Health Insurance access without corresponding accountability mechanisms. Even internal safeguards, such as requirement for multi-stakeholder panels, cross-checks with professional councils, or audit transparency have not been adequately reinforced in these proposed regulations.
3. The Bill should establish a well-structured board composition for the Authority, ensuring inclusive representation of all stakeholders within the health sector including private sector entities to promote effective oversight, balanced governance, and sector-wide accountability.
4. The Authority's mandate appears to extend into human resource management, professional conduct and training which fall squarely under existing professional regulators and the Ministry of Health's HRH units. For example, clauses around verifying individual licensure, enforcing training obligations, and inspecting for internship suitability duplicate and confuse mandates under KMPDC, NCK, and allied Acts.
5. Recommendation: Limit the Authority's Mandate
   - ✓ To improve clarity and effectiveness, the Authority's functions should be strictly limited to:
   - ✓ Oversight of health facility infrastructure and operations
   - ✓ Development of quality of care standards at facility level
   - ✓ Coordination and monitoring of patient safety systems and outcomes
   - ✓ Not regulate individual professionals, training programs, or licensure, which are better left to the existing constitutional and legal bodies.
6. The Bill lacks comprehensive mechanisms for routine reporting and analysis of medical errors and near misses, as well as structured learning systems that support continuous quality improvement. Additionally, it does not provide for patient engagement strategies or feedback loops, nor does it outline scalable and tiered quality frameworks suitable for both large and small healthcare facilities.
7. The Bill does speak to the role of the Authority and Health Facilities in establishing safe work environment for the healthcare professionals in the facilities which is a key input in quality of care and patient safety frameworks, this should also include blame free culture and an incident reporting mechanism that is free from victimization of the healthcare professionals.
8. Risk of regulatory overload without supportive infrastructure due to introduction of multiple new obligations—mandatory indemnity insurance, accreditation-linked reimbursement, regular inspections etc. without providing capacity building, funding, or tools to support implementation.
9. In line with international best practice, the role of accreditation and certification needs to be separated from the role of registration and licensing of health care facilities. Accreditation needs to be done by an independent entity, whereas the authority provides oversight e.g., KENAS provides oversight to Conformity assessment bodies in Kenya and the authority oversights KENAS *Ref from accreditation framework for Health sector Kenya 2019.* These assessments bodies can then share the data and results from the facilities with the authority for use of empanelment. The authority could in addition identify and engage independent certification bodies that would support the facilities in the accreditation process using the existing and approved quality of healthcare standards.
10. An equalization framework needs to be established by the authority for recognition of other certification frameworks and international standards aligned to KQMH framework. This will ensure that global standards and best practices are recognized and integrated into the national healthcare system.

11. Upon licensing, facilities are free to choose existing and recognized quality frameworks they prefer to pursue certification/accreditation processes in alignment with the set national standards.

Additional Comments: Global lessons and Best Practice

To help develop the best practice for the QOC Bill of Kenya, it is important to first reflect on the use of standards, licensing, quality improvement and accreditation in health systems. Use of regulations and standards is one strategy for improving quality of patient care provided in both the public and private sector. It is important that the same rules and regulations apply for the public and the private sector, especially in Kenya where over 50% of healthcare provision comes from the private sector, addressing healthcare needs from all layers of society.

Common statutory regulatory processes include licensing, certification and accreditation. However, a mechanical approach to "quality control" and inspection of inputs and processes results in static compliance with minimum standards, without stimulating human behavior towards a conscious dynamic improvement, often resulting in blame, punishment and ill-motivated staff and managers.

To be effective, most countries are following these principles when it comes to regulating and incentivizing improvement of quality of care:

- Governmental accreditation programs should not be designed as an extension of governmental "licensing" systems. Instead, accreditation of health provider institutions that comply with standards for safe and reliable care should be undertaken by a government-approved, but independent & legal third-party institution(s) that represents the interests of ministry of health, insurers, providers and patients. Healthcare providers should be able to choose an accreditation body that fits their mission, purpose and client base.
- Inspection carried out to assess whether health provider institutions comply with minimum conditions for licensing and standards for patient safety, including determining whether healthcare professionals providing those services meet the required minimum educational qualifications and credentials, should be separate from determining whether the health professionals are maximizing their training and skills through lifelong learning. The former is the role of an independent body of the ministry with a legal mandate, while the latter is the role of professional regulatory bodies which also must deal with indiscipline and malpractice within the profession. Often, inspection of health provider institutions is undertaken by medical professional councils for doctors, nurses and laboratory technicians. This could result in confusion and duplication of efforts.

Health professional training and practice standards contribute to healthcare quality and safety. Licensing is very helpful when the health care market does not adequately guard against under-qualified professionals. Licensing provides a legal underpinning for malpractice and while it provides a means to remove fraudulent or incompetent health care providers from practice, it is not enough. Therefore, in addition, re-certification is needed to ensure health care providers remain up-to-date in their knowledge and practice within the continually evolving evidence-based medicine. Licensing and re-certification by a nationwide professional body might save time and money for employers by providing a short cut to confirm that a candidate for a job meets basic qualifications.

Within the Kenyan context, regulatory reforms should ideally target five key aspects that include: the health workers, the public and private health institutions, the quality and availability of essential medical supplies and reform of public and private insurance. Moreover, and to be effective, the three regulatory processes, namely licensing, certification and accreditation, should be designed as 'separate' programmes with different objectives, incentives/ disincentives, staff and reporting structure.

1. Case Studies

Case study – Ghana

In Ghana the Health Facilities Regulatory Agency (HeFRA) Ghana's legal licensing for healthcare facilities. Professional licensing is governed by respective councils— Medical and Dental Council, Nurses and Midwifery Council and Allied Health Council. Accreditation entities, including COHSASA, offer high-level accreditation; SafeCare provides a structured, stepwise improvement path, widely used in Ghana and now incorporated into regulatory practices.

Licensing structure:

Health Facilities Regulatory Agency (HeFRA)

Established under the Health Institutions and Facilities Act, 2011 (Act 829), HeFRA is the statutory body responsible for categorizing, registering, inspecting, licensing and monitoring, all public and private healthcare facilities in Ghana. The HeFRA licensing is considered the fundamental process for assuring quality in healthcare facilities in Ghana by ensuring the basic requirement of staffing, equipment, infrastructure and facilities, etc. are in place for the services to be rendered. The licenses of facilities are renewed periodically (1 – 3 years) depending on the type of facility.

Process overview:

- Registration: Facilities apply via HeFRA's website or offices
- Inspection: HeFRA assesses facility readiness.
- Licensing: A license is issued if standards are met.
- Monitoring: Ongoing inspections ensure compliance.

Professional Councils and Accreditation Bodies

These Councils regulate and license the healthcare professionals, with licenses that are renewable annually through the required scores from continuous professional development CPD programs.

- Medical and Dental Council (MDC) regulates training and practice standards for doctors and dentists.
- Nurses and Midwifery Council (N&MC) regulates nursing and midwifery, including examinations and licensing—established under the Health Professions Regulatory Bodies Act, 2013 (Act 857).
- Allied Health Professions Council oversees training, accreditation, licensing, and regulation of allied health professionals, also under Act 857.

National Health Insurance Authority - Credentialing

The Authority employs credentialing processes to verify the licenses, qualifications, experience, and competence of the healthcare providers to deliver safe and effective care. It is the processes through which the Authority determines which facilities are allowed to be empaneled in an insurance scheme, to receive subscribers. The outcome of the credentialing process determines the facility's tariff assigned, and credentialing is renewed every two years.

COHSASA (Council for Health Service Accreditation of Southern Africa)

A not-for-profit accreditation body founded in South Africa in the mid-1990s. It offers accreditation programs for a wide range of healthcare facility types—from clinics to tertiary hospitals—and is internationally accredited by ISQua.

SafeCare

Established in 2011, SafeCare is a stepwise quality improvement and certification system, created by a partnership of COHSASA, PharmAccess (Netherlands), and Joint Commission International. Designed for low-resource settings, SafeCare provides a graded approach—facilities earn "Certificates of Improvement" from Level 1 (basic) to Level 5 (advanced). Achieving Level 5 can prepare facilities for full accreditation by COHSASA or JCI.

2.Case study in the Netherlands:

Healthcare Accreditation and Licensing Structure in The Netherlands

In the Netherlands, healthcare accreditation and licensing operate within a tightly regulated framework to ensure high-quality care, patient safety, and professional accountability. The system is overseen by the Ministry of Health, Welfare and Sport (VWS), in collaboration with independent regulatory and professional bodies.

Licensing Structure

1. **Institutional Licensing**

   Healthcare institutions must be licensed under the Healthcare Institutions Admission Act. This allows them to legally operate and receive funding under the Dutch Health Insurance Act.

2. **Professional Licensing**

   Healthcare professionals are licensed through the **BIG-register**, under the **BIG Act**. This register ensures that professionals (e.g., doctors, nurses, pharmacists) meet the required educational and ethical standards to practice.

Accreditation Structure

1. **Institutional Accreditation**

   Accreditation of healthcare institutions is **voluntary** but widely adopted to ensure and demonstrate quality improvement. Dutch organizations such as the **Nederlands**

Instituut voor Accreditatie in de Zorg (NIAZ) offer assessments based on internationally recognized (Isqua) standards.

2. **Professional Accreditation and Revalidation**

Healthcare professionals maintain their BIG registration through **Continuous Professional Development (CPD)**, revalidation, and in some cases, participation in professional peer review and audit systems.

Role of International Accreditation Bodies in the Netherlands

International accreditation bodies like **Joint Commission International (JCI)** and **ISQua** (International Society for Quality in Health Care) play an important influential role by:

- **Providing globally recognized quality benchmarks** for Dutch hospitals that serve international patients or seek international reputation.
- **Enhancing internal quality systems** through external peer-reviewed audits aligned with global best practices.
- Supporting harmonization with **European and international healthcare standards**, which is particularly relevant for cross-border care and international collaboration.
- Acting as reference points for **Dutch national accrediting bodies** (e.g., NIAZ), many of which align their methodologies with ISQua principles for broader credibility.

Interplay Between Licensing and Accreditation

- **Licensing is mandatory** and ensures legal and professional compliance, while **accreditation is voluntary** and focused on continuous improvement.
- Accreditation can positively influence institutional reputation, patient trust, and even financial contracts with insurers.

In summary, the Dutch system integrates **mandatory licensing** with **voluntary national and international accreditation**, forming a robust framework for quality assurance, professional accountability, and international alignment in healthcare delivery. Healthcare providers may choose an accreditation body that meets that purpose. This can be local body NIAZ, but also international body JCI. Large hospitals that cater to international patients tend to prefer JCI accreditation, whereas smaller regional hospitals choose the Dutch accreditation body NIAZ.

Case study in the US

Each U.S. state mandates healthcare facilities operating within its jurisdiction to obtain and maintain a license. State licensure laws typically govern:

State departments of health are responsible for inspecting facilities for compliance with these laws, often through their own surveyors or third-party contractors. These inspections may occur every 1 to 3 years, depending on state policy and facility type (e.g., hospitals, ambulatory surgery centers, long-term care).

Although accreditation and licensure are distinct, there is substantial overlap in the domains they assess. Many states have moved toward recognizing national accreditation by organizations like the Joint Commission (and by extension, JCI standards in aligned global

facilities) as a proxy for part or all of state inspection requirements. This process, known as "deemed status," reflects:

- **Reduced duplication:** If a hospital is accredited by a recognized body, states may waive some or all inspection requirements.
- **Standard harmonization:** States align their regulatory expectations with those developed by private accreditation bodies.

For instance:

- **California and New York** accept Joint Commission accreditation for hospital licensure compliance but retain authority to inspect under specific complaints or adverse events.
- **Texas and Florida** perform risk-based inspections, placing less frequent scrutiny on accredited hospitals.

Case study in Thailand

Healthcare Accreditation and Licensing Structure in Thailand

As of 2019, Thailand's population of 68 million is served by 927 government hospitals and 363 private hospitals with 9,768 primary care health units (SHPH clinics), responsible for Thai citizens' health at the sub-district level.

Universal health care is provided through three programs: the civil service welfare system for civil servants and their families, Social Security for private employees, and the universal coverage scheme, introduced in 2002, which is available to all other Thai nationals. Some private hospitals are participants in the programs, but most are financed by patient self-payment and private insurance. According to the World Bank, under Thailand's health schemes, 99.5 percent of the population have health protection coverage.

Thailand has a multi-layered healthcare licensing and accreditation structure, combining mandatory government licensing under the Medical Facility Act with voluntary national and international accreditation programs. The Healthcare Accreditation Institute (HAI) runs the national Hospital Accreditation (HA) program, while international bodies like Joint Commission International (JCI) provide global certification. Facilities must also adhere to regulations from the Thai Food and Drug Administration (TFDA) for product and service quality.

Licensing Structure

Licensing for healthcare organizations is mandatory.

This act requires hospitals to obtain two types of licenses to operate:

- a license to operate a medical facility, granted to the facility owner for 10 years and:
- a license to manage a medical facility granted to the supervising medical professional for two years.

Accreditation Structure

Accreditation for healthcare institutions is voluntary.

- **The Healthcare Accreditation Institute (HAI)** develops and implements standards to assess and certify the quality of healthcare facilities nationwide.

The Healthcare Accreditation Institute (HAI) is a public organization responsible for quality improvement and accreditation of healthcare organizations in Thailand. The status as a government agency enhances the credibility of the Institute and provides HAI getting some budget support from the government. The institute has been accredited by an international organization, The International Society for Quality in Health Care External Evaluation Association (IEEA).

Role of International Accreditation Bodies in the Thailand

- Many Thai hospitals voluntarily seek accreditation from international bodies like Joint Commission International (JCI).
- JCI accreditation is considered a global "gold standard" for quality and patient safety standards.
- Thailand has a high number of JCI-accredited hospitals, particularly in the private sector.
- As of February 2025, there are 63 Joint Commission International (JCI)-accredited medical institutes in Thailand, making it a leading country in the Asia-Pacific region for high-quality, internationally recognized healthcare facilities. These accreditations highlight the Thai healthcare sector's commitment to patient safety and quality of care, which has helped establish Thailand as a top destination for medical tourism.

Interplay Between Licensing and Accreditation

In summary, the Thai system integrates **mandatory licensing** with **voluntary national and international accreditation**, forming a robust framework for quality assurance, professional accountability, and international alignment in healthcare delivery.

Kenya now has the opportunity to move beyond minimum compliance and punitive inspections, and instead build a reformed regulatory framework where licensing, certification, and independent accreditation serve as complementary pillars. Anchored on clear roles and accountability, this framework will transform the Quality Healthcare and Patient Safety Bill from a compliance exercise into a powerful driver of continuous improvement, patient safety, public trust, and universal health coverage in Kenya.

Committee resolution: The Committee noted the general comments by KHF.

38. THE KENYA NATIONAL COMMISSION ON HUMAN RIGHTS (KNCHR)

The Kenya National Commission on Human Rights (KNCHR) submitted as follows;

a) **Clause 2**

Introduce definitions of the terms quality improvement and quality assessment.

Justification: For clarity and to help avoid ambiguity in their interpretation and application.

Committee resolution: Not adopted. The terms are used in their ordinary sense.

b) **Clause 3**

Amend clause 3(d) to: "(d) ensure health facilities provide healthcare services in a manner that guarantees availability, accessibility, acceptability and quality".

Justification: To align with the "Availability, Accessibility, Acceptability, Quality" (AAAQ) framework under General Comment No. 14 on the Right to the Highest Attainable Standard of Health developed by the Committee on Economic, Social and Cultural Rights based on article 12 of the International Covenant on Economic, Social and Cultural Rights which Kenya is a signatory. The Commission contends that as the Bill seeks to give effect to Article 43 (1)(a), the right to health in all its forms and at all levels must cover the interrelated and essential elements, and applied in accordance to the AAAQ framework expounded as follows:

- Availability- guaranteeing that functioning public health and health-care facilities, goods and services, as well as programmes, are available in sufficient quantity. This includes other determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical personnel and essential drugs;
- Accessibility- guaranteeing that health facilities, goods and services have to be accessible to everyone without discrimination. This includes overlapping dimensions such as physical accessibility where health facilities, goods and services are to be within safe physical reach for all sections of the population; economic accessibility (affordability) of health facilities, goods and services must be affordable for all; and information accessibility regarding the right to seek, receive and impart information and ideas concerning health issues to all persons seeking healthcare services including persons with disabilities.
- Acceptability- guaranteeing that all health facilities, goods and services are respectful of medical ethics and culturally appropriate to individuals, minorities and communities, as well as being designed to respect confidentiality and improve the health status of those concerned.
- Quality- guaranteeing that aside from being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate hospital sanitation.

Committee resolution: Not adopted. The clause is in order as drafted and takes into account the proposed aspects.

c) Clause 6

Proposed the introduction of a new clause to provide for the right to maternal care, with the following rights:

i. The right to be free from physical violence and verbal abuse during labour and childbirth;
ii. The right to be free from discrimination during labour and childbirth;
iii. The right to a dignified and respectful care – including being granted acceptable levels of privacy and confidentiality during labour and childbirth.

Justification: To implement the Court of Appeal decision in County Government of Bungoma & 2 others v. Josephine Oundo Ongwen (AKA Josephine Majani) & 2 Others where the Court deployed the minimum core threshold to the right to health that must be realized immediately and is not subject to progressive realization, thereby framing the proposed rights to constitute the minimum core of a woman's right to respectful maternal care during child

birth. It is important to promulgate this landmark Court decision through the proposed Bill as it seeks to guarantee the quality of care and overall best health outcomes for all patients as a positive step towards a human rights-based maternity care, where dignified and respectful care experiences for women during childbirth, free from violence and discrimination should be the new norm.

Committee resolution: Not adopted. The clause is in order as drafted.The definition of "healthcare services" includes maternal care.

d) Clause 8

Clause 8(2)(c) be amended to read as follows "(c) provide reasonable accommodation to patients with disabilities"

Justification: To expand the mandate of health facilities beyond physical accessibility to the broader component of reasonable accommodation. Section 2 of the Persons with Disabilities Act, 2025 defines reasonable accommodation as necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms. The Commission notes that health facilities should be mandated to provide reasonable accommodation to cover aspects such as sign language interpreters, offering large print or braille materials health information products/information, ensuring physical accessibility of equipment like accessible exam tables and ramps among others. These holistic accommodations over and above physical accessibility would ensure patients with disabilities receive healthcare on an equal basis with others as provided under Section 24 of the Persons with Disabilities Act, 2025.

Committee resolution: Not adopted. The clause is in order as drafted. The Persons with Disabilities Act, 2025 makes adequate provision for access to healthcare by persons with disabilities.

e) Clause 15

Clause 15 (2)(b) be amended to cover all the discriminatory grounds provided under Article 27 (4) of the Constitution so as to read as follows: "15(2)(b)non-discriminatory treatment regardless of race, sex, pregnancy, marital status, health status, ethnic or social origin, colour, age, disability, religion, conscience, belief, culture, dress, language or birth."

Justification: To align with Article 27 (4) of the Constitution.

Committee resolution: Not adopted. The clause is in order as drafted. The other issues apply even without being expressly listed.

f) Clause 29

Clause 29 (2) be amended as follows: "29 (2) The appointment under this section shall be by notice in the Gazette."

Justification: It is good governance practice to provide for the gazettement of all the members of the Board of Directors of the Authority and not just a segment as currently proposed. This is critical in formalizing their legal standing and pave way for commencement of official duties under the proposed legislation.

Committee resolution: Not adopted. The clause is in order as drafted. The other Board members hold office by virtue of their appointment.

g) **Clause 46**

i. Clause 46 be amended by introducing a new paragraph to mandate the Authority to adhere to Fair Administrative Action Act, Cap. 7L in when considering suspension or revocation of certificate of registration of health facilities.

Justification: To align with the provisions of the Fair Administrative Action Act, Cap. 7L.

Committee resolution: Not adopted. The clause is in order as drafted. The provisions of the Fair Administrative Action Act, Cap. 7L apply even without the same being restated.

ii. Introduction of a new clause 46 (5) as follows: "46. (5) The Authority shall Gazette the details of a health facility whose certificate of registration has been suspended or reinstated."

Justification: To officially notify the public through a notice in the Gazette regarding information on health facilities whose certificates of registration suspended or reinstated. This is crucial in safeguarding the quality of healthcare and patient safety. This is also in taking cue from clause 47 (4) which provides for Gazettement of details of health facilities whose certificate of registration has been revoked.

Committee resolution: Not adopted. The clause is in order as drafted. The Authority will list the same on its website.

h) **Clause 47**

Clause 47 be amended by introducing a new paragraph to mandate the Authority to adhere to Fair Administrative Action Act, Cap. 7L in when considering suspension or revocation of certificate of registration of health facilities.

Justification: To align with the provisions of the Fair Administrative Action Act, Cap. 7L.

Committee resolution: Not adopted. The clause is in order as drafted. The provisions of the Fair Administrative Action Act, Cap. 7L apply even without the same being restated.

i) **Clause 53**

Clause 53 be amended by introducing a new sub-clause immediately after clause 53 (2) to read as below and renumber the clauses accordingly: "53 (3). Health facilities shall not demand for prepayment of prospective medical costs as a condition for the provision of emergency medical treatment."

Justification: Article 43 (2) of the Constitution provides that a person shall not be denied emergency medical treatment and this is also guaranteed under Section 7 of the Health Act, Cap. 241. The Commission notes that the proposed legislation already defines emergency medical treatment and guarantees quality of health care in a way that ensures healthcare services are safe, effective, timely, efficient, equitable, and people centered, provided to an individual, that improves health outcomes based on evidence-based standards. Thus, the Commission contends that in order to achieve patient safety, quality of care and desirable health outcomes as provided in the Bill, health facilities are to be mandated to respect and ensure realization of the right to emergency medical treatment under Article 43 (2) in the first instance.

Committee resolution: Not adopted. The clause is in order as drafted. The right to emergency medical treatment is already guaranteed under the Constitution.

j) **Clause 55**

Introduction of a new clause 55 (6) as follows: "55. (6) The Authority shall Gazette the details of a health facility whose licence has been revoked."

Justification: To officially notify the public through a notice in the Gazette regarding information on health facilities whose certificates of registration suspended or reinstated. This is crucial in safeguarding the quality of healthcare and patient safety.This is also in taking cue from clause 47 (4) which provides for Gazettement of details of health facilities whose certificate of registration has been revoked.

Committee resolution: Not adopted. The clause is in order as drafted. The Authority will list the same on its website.

k) **Clause 65**

A new paragraph be introduced in clause 65 immediately before paragraph (a) to read as below and reorganize the numbering correctly: 65. (a) designate a quality improvement team with clear terms of reference;".

Justification: A dedicated quality improvement team will enhance accountability and compliance to the proposed quality improvement programs under clause 22 (2) relating service gaps, prioritizing maternal healthcare, primary healthcare, mental healthcare and emergency medical treatment among others. This will also be in line with Ministry of Health's Kenya Quality Model for Health.

Committee resolution: Not adopted. This will be set out in subsidiary legislation.

l) **Clause 67**

A new paragraph be introduced under clause 67 to provide for the timeline within which the Authority is required to undertake quality assessment of a health facility and award of a performance rating.

Justification: Provision for a timeline enhances predictability and sustainability of quality improvement programs by health facilities as well as mandating the Authority to act on the health facilities' self-assessment reports by way of performance scoring within timelines to be stipulated. This ensures overall compliance on quality improvements by both health facilities and the Authority. This will also be in accordance with Clause 70 (3)(h) which makes it mandatory for the register of registered, licensed and accredited health facilities to contain information quality rating and scores.

Committee resolution: Not adopted. This will be set out in subsidiary legislation.

m) **Clause 75**

Clause 75 be deleted.

Justification: For legislative harmony and to avoid duplication since the provision in Clause 75 has already been made under Clause 72 (1).

Committee resolution: Not adopted. There is need to expressly empower the Authority to appoint and gazette inspector.

n) **Clause 83**

i. Clause 83 (4) be amended to cap the number of Health Care Tribunal member to not more than seven (7).

Justification: To make the Tribunal effective and efficient in the discharge of its functions. The Commission also wishes to point out that Tribunals established under existing legislation frameworks highlighted below have set a maximum of seven (7) members for a Tribunal hence the need to align the clause on Tribunal membership in the proposed Bill to the existing frameworks as below:

- The Education Appeals Tribunal- 7 members
- The Political Parties Disputes Tribunal- 7 members
- The HIV and AIDS Tribunal- 7 members
- The Micro and Small Enterprises Tribunal- 6 members
- The National Civil Aviation Administrative Review Tribunal-6 members
- The Competition Tribunal- 5 members

Committee resolution: Not adopted. The Tribunal composition is in order as the Tribunal will be handling many disputes and complaints.

Clause 83 (7) be amended by replacing the words "Cabinet Secretary" with "Judicial Service Commission" to read as follows: "83 (7). 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."

Justification: The Court of Appeal in Attorney General v Okoiti & 3 others [2025] KECA 309 (KLR) affirmed the High Court decision among others, that Tribunals established pursuant to article 169(1)(d) of the Constitution of Kenya, 2010 are not part of the Executive machinery, nor are they independent adjudicatory bodies, but are subordinate courts which are an integral part of the Judiciary. Further, the Commission notes that the National Assembly Departmental Committee on Justice and Legal Affairs while considering the Tribunals Bill, 2023 (Bill lapsed) observed that since the tribunals are being transited to the Judiciary, the remuneration of the members of the should be determined by the JSC in consultation with SRC

Committee resolution: Adopted. Tribunals fall within the ambit of the Judiciary.

ii. Clause 83 (8) of the Bill be amended by replacing the words "Cabinet Secretary" with "Chief Justice" so as to read as follows "83 (8). The Chief Justice shall make rules for operationalization of the Tribunal."

Justification: The Court of Appeal in Attorney General v Okoiti & 3 others [2025] KECA 309 (KLR) affirmed the High Court decision, among others, that Tribunals established pursuant to article 169(1)(d) of the Constitution of Kenya, 2010 are not part of the Executive machinery, nor are they independent adjudicatory bodies, but are subordinate courts which are an integral part of the Judiciary. Further, the Commission notes that the National Assembly Departmental Committee on Justice and Legal Affairs while considering the Tribunals Bill, 2023 (Bill lapsed) observed that the Chief Justice should be the one responsible for making rules governing Tribunals.

Committee resolution: Adopted. Tribunals fall within the ambit of the Judiciary.

o) Clause 97

Clause 97 be amended by introducing further offences as below:

"(f) demands or permits the demand of payment of prospective medical fees or admission fees prior to providing emergency medical treatment;
(g) detains or permits the detention of the body of a deceased patient for purposes of enforcing settlement of pending medical bills".

Justification: To give effect and ensure realization of the right to emergency medical treatment as provided under Article 43 (2) and section 7 of the Health Act. Cap. 241. The Bill already makes provision for emergency medical treatment as a quality standard hence the provision for an offence and corresponding penalty will ensure enforcement and compliance. Further, to expand the concept of patient dignity by restraining health facilities from withholding or detaining the body of a deceased patient for purposes of enforcing settlement of pending medical bills in accordance with the High Court decision in Mary Nyang'anyi Nyaigero & another v Karen Hospital Limited & another [2016] KEHC 6882 (KLR) which held that hospital bills are civil debts which can lawfully be recovered by following the civil process not by detaining a body that has no monetary value.

Committee resolution: Not adopted. The offences are sufficient as drafted. Issues of prospective medical costs and detention of dead bodies ought to be provided for in a different legal framework.

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENTS

Paragraph 10

Clause 101 (10) seeks to amend Section 112 of the Health Act is amended by deleting paragraph (a) and (d) deleting paragraph (e). The Commission proposes that the proposed amendments be dropped.

Justification: The proposed Bill does not provide for the fees to be paid to access services in a public health facility other than fees for registration, licensing and accreditation of health facilities. The Commission notes that deletion of paragraph 10 (a) of Section 112 of the Health Act leaves an incurable lacuna. The Commission further notes that the proposed deletion of paragraph 10 (e) of Section 112 of the Health Act leaves a gap in that the proposed Bill only prescribes that the Authority shall keep a register of registered, licensed and accredited of health facilities and does not extensively cover the nature of returns, registers, reports, records, documents and forms to be completed and kept by health facilities. The Commission is of the view that the two paragraphs should be left intact as is in the Health Act, 2017.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 35

Clause 101 (35) seeks to amend the Medical Practitioners and Dentists Act by repealing section 17. The Commission recommends that the proposed amendment be dropped.

Justification: The Bill repeals Section 17 on recovery of fees by practitioners. KMPDC proposes amending instead, to specify that only practitioners licensed under Section 14 may recover fees. Section 17 of the Medical Practitioners and Dentists Act, Cap 253 provides a

critical safeguard on patient safety and quality of care by ensuring that unregistered practitioners do not purport to offer and charge for services they are not licensed to offer in the first instance.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 113

Clause 101 (113) of the Bill proposes to amend the Social Health Insurance Act by repealing PART VIII of the Act. The Commission proposes that Section 43 (1) of the Act be retained to introduce the whole aspect of the Tribunal and to read as below: "43. Health Care Tribunal (1) A person aggrieved by a decision made under this Act may, within one month from the date of the decision, appeal to the Health Care Tribunal for a review of such decision."

Justification: Part VIII of the Social Health Insurance Act is essential in introducing and directing aggrieved parties to the Health Care Tribunal established under the proposed Bill. As currently proposed, the total repeal will only result to the Tribunal being referenced in the definition part under section 2 of the Act and nowhere else.

Committee resolution: Adopted with amendments. The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

General Comments on the Bill by the Kenya National Commission on Human Rights (KNCHR)

1. The Commission welcomes the provisions of the Bill seeking to give effect to Article 43 (1) of the Constitution; to provide for the responsibility of the national and county governments in the realization of quality of healthcare for patients; to provide for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, registration, licensing and accreditation of health facilities; to provide for the setting of standards for quality of healthcare; among others.

2. The Commission notes that the objects and the guiding principles of the proposed legislation lay the basis for ensuring that health facilities provide healthcare services in a manner that guarantees high quality care, safety, effectiveness and efficiency, which the Commission proposes that the Bill be amended to refer to and guarantee the highest attainable standards of healthcare by ensuring that healthcare services provided by both public and private health facilities meet the availability, accessibility, acceptability and quality (AAAQ) framework under General Comment No. 14 on the Right to the Highest Attainable Standard of Health developed by the Committee on Economic, Social and Cultural Rights.

3. The rights-based and patient-centred care under Part II of the Bill is welcome. The specific rights include the right to safe and accessible health facilities (clause 8); right to care by a qualified health professional (clause 9); right to information and decision-making (clause 10); right to safe and quality care (clause 11); right to timely and effective care (clause 12); right to safe processes and practices (clause 13); right to safe and quality health products and technologies (clause 14); right to dignity and equity (clause 15); right to be heard (clause 16). The Commission however notes the need to expressly provide for the right to maternal care following the Court of Appeal decision in County Government of Bungoma & 2 others v. Josephine Oundo Ongwen (AKA

Josephine Majani) & 2 Others that there is a minimum core threshold to the right to health that must be realized immediately and is not subject to progressive realization.

4. The right to emergency medical treatment is Constitutionally guaranteed under Article 43 (2) and further provided under Section 7 of the Health Act, Cap. 241. While the Bill has defined emergency medical treatment, the Commission notes the need to provide categorically that health facilities shall not demand for prepayment of prospective medical costs as a condition for the provision of emergency medical treatment. This is important to ensure the realization of the right to emergency medical treatment and overall quality and health outcomes for patients as provided in the Bill, noting that facilities have the tendency of demanding payments upfront.

5. The Bill also seeks to ensure patients access quality healthcare services that are safe and dignified. The Commission holds the view that the concept of patient dignity ought to be expanded by restraining health facilities from withholding or detaining the body of a deceased patient for purposes of enforcing settlement of pending medical bills. The High Court in Mary Nyang'anyi Nyaigero & another v Karen Hospital Limited & another [2016] KEHC 6882 (KLR) held that hospital bills are civil debts which can lawfully be recovered by following the civil process not by detaining a body that has no monetary value.

6. The Commission notes that whereas the Bill seeks to amalgamate the role of registration, licensing, accreditation and inspection of health facilities to safeguard and ensure quality standards of care, there will be need for close collaboration between the Authority and regulatory bodies in place. Further, the inspectors that will be engaged by the Authority must possess relevant professional expertise for the health facilities they are to assess.

7. The Commission also welcomes the requirement to the effect that compliance to quality improvement standards shall form the basis for health facility accreditation, performance assessment and access to the Social Health Insurance Fund. This ensures that facilities must undergo periodic reviews and submit information to the Authority to demonstrate that they meet prescribed quality standards to bill SHA for health insurance services.

8. The Commission acknowledges the Bill for seeking to provide for a rights-based and patient-centred healthcare system through setting of standards for healthcare services and health facilities in a manner that secures the protection, promotion, improvement and maintenance of the health and well-being of every person. The proposed legislation also presents a vital opportunity to transform Kenya's healthcare governance landscape in terms of registration, licensing, accreditation and inspection of health facilities to ensure quality of care, patient safety and rights. The Commission notes that the Authority contemplated in the Bill will need to closely collaborate with relevant regulatory bodies in the performance of its functions. The Commission urges that extensive consultation with sector players should be conducted during the development of regulations contemplated under the Bill for successful implementation of the proposed quality improvement initiatives. Lastly, the Commission calls for full implementation of the health laws as well as adequate budgetary allocation by both the National and County governments in line with the Abuja Declaration to guarantee the realization of the right to the highest attainable standard of healthcare provided under Article 43 of the Constitution.

Committee resolution: The Committee noted the general comments by KNCHR.

39. THE NATIONAL GENDER AND EQUALITY COMMISSION (NGEC)

The National Gender And Equality Commission (NGEC) submitted as follows;

a) **Clause 2**

i. Introduce the following new proposed interpretations:

"Age-appropriate" means suitable for a particular age or age group

Justification: The term has been proposed in an amendment to clause 11(1)(b).

Committee resolution: Not adopted. The term is used in its ordinary sense.

ii. "Geriatrics" means a specialized branch of medicine focused on the health care of older adults

Justification: Older persons face a lot of discrimination and negative bias in health facilities leading to poorer quality of care and reduced access to services. The Commission has applied the term through a proposed amendment to clause 15 on Right to Dignity and Equity (serial 7 below). Article 57(c) obligates the state to ensure older persons live in dignity and respect and be free of abuse.

Committee resolution: Not adopted. The proposed term has not been used in the text of the Bill.

iii. "Non-Informed Consent" occurs when an individual agrees to a medical procedure or study without being fully aware of the potential risks, benefits, and alternatives

Justification: The Commission has proposed sanctions in a new clause 10(4).

Committee resolution: Not adopted. The proposed term has not been used in the text of the Bill.

b) **Clause 4**

Amend by inserting an additional principle as follows "(e) Promotion of a human rights-based approach to health care".

Justification: The proposed Bill has not considered a rights-based approach to deal with patients. To move away from charity and other models that put patients at the mercy of health workers. Rights-based means integrating human rights principles and standards in all aspects of health care. Article 43(1)(a) of the Constitution provides the right that the proposed law seeks to implement. This principle is also very crucial in dealing with issues of persons with mental and psychosocial disabilities.

Committee resolution: Not adopted. The Bill provisions incorporates the rights-based approach as it specifies the rights of patients.

c) **Clause 5**

Substitute the subtitle "Cabinet Secretary" with "National Government"

Justification: Obligations placement in line with the Functions of the National Government in the Fourth Schedule of the Constitution. The proposal also aligns with Section 15 of the Health Act, which recognizes the functions as the National Government's functions.

Committee resolution: Not adopted. The Bill has adopted the House drafting style.

d) **Clause 6**

i. Proposed a new clause on the rights of persons under incarceration and insert as follows: "All correctional facilities shall ensure that all persons under incarceration have access to timely and quality healthcare'. Further proposed amendment of clause 94 on Regulations to mandate the Cabinet Secretary to make regulations on access to health care by persons in incarceration.

Justification: The Right in Article 43 needs to protect the rights of all persons, including those who are in prison and correctional facilities. The Nelson Mandela Rules are internationally recognized guidelines that promote the health Rights of Prisoners.

Committee resolution: Not adopted. The Bill applies to all persons including incarcerated persons.

ii. Introduce a new provision on the right of discharge from health Facilities and amend by inserting a new clause as follows-;

a. Every patient has the right to be discharged from a health facility once they are medically fit for discharge
b. Health facilities shall take all reasonable steps to prevent unnecessary delays that may prolong a patient's stay beyond their medical needs
c. Under no circumstances shall a facility detain or deny discharge to a patient on account of failure to pay hospital fees.

Justification: To ensure that once a patient is due for discharge, the same should be expedited and any other pending matters to be attended to while out of hospital. Some health facilities detain patients who are unable to settle the fees and ironically continue charging them inflating the amount even further.

Committee resolution: Not adopted. The proposed issues are best handled in a different legal framework.

e) **Clause 8**

i. Amend 8(2) (c) by inserting after the phrase "modification" the following: "and accommodation.

Justification: Reasonable accommodation has not been provided in the proposed law. The Commission has proposed the interpretation of the two terms, i.e, accommodation and modification

Committee resolution: Not adopted. Accommodation includes issues of modification.

ii. Insert a new clause 8(4) as follows: "A health care worker who commits an offence under this section shall be liable, on conviction, to a fine not exceeding one hundred shillings or to imprisonment for a term not exceeding six months, or to both".

Justification: The objectives of a law are to deter non-compliance and sanction the breach thereof. There are no sanctions prescribed for abuse, violence, and or neglect.

Committee resolution: Not adopted. There is no need for the offence as the same is set out in the Health Act, Cap. 241.

f) **Clause 10**

i. Insert a new subclause 10(3) as follows "a patient has the right not to be subjected to unauthorized and non-informed medical procedures".

Justification: Cases of violation of the rights of patients has also been on the rise especially for women with various disabilities by health workers in collaboration with the family.

Committee resolution: Not adopted. This is already provided for under the Bill and the Health Act, Cap. 241.

ii. Amend by inserting another subclause (4) on sanctions as follows:
"(4)(a)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.
(b) The health worker will face sanctions from their respectful professional bodies
(c) The patient can institute civil proceeding to recover damages"

Committee resolution: Not adopted. There is no need for the offence as the same is set out in the Health Act, Cap. 241.

g) **Clause 15**

i. Amend clause 15(2)(a) by inserting after the phrase "including" the words "geriatric care," and amend clause 15(2) (c) by inserting after the phrase "disabilities" the following:" older members of society and Intersex persons"

Justification: Older members of society and intersex persons are not included. Health care needs to specifically focus on older members of society because of the increased health complications and intersex persons who are very vulnerable and susceptible to multiple discrimination

Committee resolution: Not adopted. Healthcare services are to be provided for all persons including older members of society and Intersex persons.

ii. Amend by deleting the phrase "minority groups" without replacement.

Justification: The Constitution of Kenya, in Article 260, by way of deduction, defines marginalized groups to include minority groups. It does not provide for an express interpretation of "Minority groups,".

Committee resolution: Not adopted. Minority groups need to be acknowledged since they are recognized under the Constitution.

h) **Clause 24**

Need to look into the applicability of professional indemnity

Justification: Substantiate whether professional indemnity is applicable to both public and private health facilities and consider making an exception to government health facilities but providing a mechanism by an easy to access, procedurally simplified and expeditious process

for aggrieved patients to follow.The process under the Kenya Medical Practitioners and Dentist Council faces severe challenges including:

1.Accessibility and Awareness: The process is not well-publicized, and many stakeholders including patients and healthcare workers who are unaware of how to lodge complaints or follow up on them.
2.Undefined Timelines: Although the Council states that it aims to resolve matters "at the shortest time possible," there are no statutory timelines for each stage of the complaint process.
3.Overly Technical Procedures: The disciplinary rules (e.g., Legal Notice No. 171 of 2022) involve formal inquiries, notices, and hearings that resemble court proceedings.
4.Lack of Transparency: There is minimal public reporting on the outcomes of disciplinary cases. It's unclear how many complaints are received, investigated, or result in sanctions.

Committee resolution: Not adopted. The clause is in order as drafted as the specifics of professional indemnity will set out in subsidiary legislation.

i) **Clause 29**

Amend clause 29(1)(h) by substituting the proposed appointee with "One person representing persons with disability nominated by the umbrella organization of persons with disabilities.

Committee resolution: Not adopted. The provision makes provision for a member of the public which may include persons with disbailities.

Amend clause 29 further by providing for-

a. gender balance and representation of persons with disabilities
b. appointment of directors in a staggered manner to ensure Board business does not stagnate at any given time.

Justification: The proposed person is ambiguous and does not provide a criteria for the nomination. The proposal by the Commission aligns with the principle of inclusion of persons with disabilities and also provides a criterion for nomination. Non-compliance with Mwongozo code for governance and the Constitution on inclusion and equality. Principle of gender balance and representation of Disability.

Committee resolution: Not adopted. Issues of gender and staggering of appointments are handled as a matter of practice.

j) **Clause 31**

Amend by providing grounds of vacation of office as follows-:
(a) Resignation
(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) violation of the Constitution or any other written law; or

Justification: The provision has not been provided in the Bill

Committee resolution: Not adopted. These provisions are applied as a matter of practice in some instances.

k) **Clause 36**

Amend by deleting the provision in 36 (a) and (f) that refer to mental infirmity and unsound mind

Justification: Vacation of office by the Board members and the Chief Executive Officer on the grounds of mental infirmity or unsound mind is prejudicial to persons. The Bill is, on one hand, proposing the rights of all patients, including persons with mental disabilities, while on the other, it is discriminating against them by referring to them in derogatory terms like "unsound mind." The Ministry of Health has rolled out the WHO Quality Rights Initiative, which seeks to improve the quality of mental health and protect the rights of persons with mental health conditions. The Convention on the Rights of Persons with Disabilities also provides for reasonable accommodation, and if it is no longer viable, then the due process of separation takes its course. This ground does not need to be legislated in all frameworks because it is discriminatory and prejudicial against persons with various forms of disabilities

Committee resolution: Not adopted. The terms are used in the same manner as used in the Constitution and Mwongozo.

l) **Clause 94**

Amend clause 94(2) by substituting "60 days" with "30 days".

Justification: The period of 60 days in 94(2) is too long and unjustifiable, depending on the subject of the review.

Committee resolution: Not adopted. The clause is in order as drafted as sixty days allows for seamless consideration of a review of a decision by the Authority.

m) **Clause 98**

Amend Clause 98 by substituting "ten Million" with "one hundred thousand" and "ten years" with "six months".

Justification: The general penalty for unidentified offences is ambiguous and excessive in the circumstances. We note that the penalties for identified offences in Clauses 78,82, and 97 are way below the proposed penalty in this provision

Committee resolution: Not adopted. The general penalty is commensurate to the other type of offences and penalties under the Bill.

6. PSK-NAIROBI BRANCH

a) Clause 6

In relation to clause 6(g), insert a new subsection immediately after Clause 6 (G): "Subsection H. The provision of this act shall be subject to further control of the Strategic Goods Act."

Justification: The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.

Committee resolution: Not adopted. This is beyond the scope of the Bill.

b) Clause 8

In relation to clause 8(2)(d) on "Respond to medical emergencies and make provision for access to emergency medical care through the national health emergency communication centre maintained by the Digital Health Agency", Insert a new subsection immediately Clause Subsection 2 (d): "Subsection 2 (e) The provision of this act shall be subject to further control of the Strategic Goods Act."

Justification: The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.

Committee resolution: Not adopted. This is beyond the scope of the Bill.

c) Clause 21

In relation to clause 21(1)(b), Insert of a New subsection immediately after Clause (c) 'Subsection H. The provision of this act shall be subject to further control of the Strategic Goods Act."

Justification: The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.

Committee resolution: Not adopted. This is beyond the scope of the Bill.

d) Clause 44

- In relation to clause 44(1)(b), Insert a new subsection after Clause 46 (b) "iv. That application must be accompanied by registration of the superintendent of the facility and the superintendent of each department, including speciality clinics, in one unified licence."

- In relation to clause 44(1)(d), insert registered and retained under this Act.

Justification: This reduces the risk of double jeopardy for healthcare professionals who pay professional fees to different authorities and introduces a unified licence.

Committee resolution: Not adopted. The clause is in order as drafted. Issues of superintendent may be handled in subsidiary legislation.

e) Clause 48

Insert a new subsection (2) after subsection 1. (2)A person who wishes to operate a health facility shall, after being registered under section 47, apply for an annual licence for all superintendents of each department, each speciality clinic and health professionals"

Justification: This reduces the risk of double jeopardy for healthcare professionals who pay professional fees to different authorities and introduces a unified licence.

Committee resolution: Not adopted. The clause is in order as drafted. Issues of superintendent may be handled in subsidiary legislation.

f) Clause 58

Insert of a New subsection immediately after sub-clause (h) in clause 58(5)—" (i) The provision of this act shall be subject to further control of the Strategic Goods Act."

Justification: The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.

Committee resolution: Not adopted. This is beyond the scope of the Bill.

g) Clause 70

In relation to clause 70(3)(g), Insert Subsection H after G. "The provision of this Act shall be subject to further control of the Strategic Goods Act."

Justification: The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.

Committee resolution: Not adopted. This is beyond the scope of the Bill.

h) Clause 94

In relation to the Regulations on (q) categories of health facilities, all Premises are in the **Addendum 1** as aligned and assign all healthcare professionals connected thereof and incidental to the Amendment of CAP 241 Section B, CAP 244, CAP 245 and any other act before the bill is enacted to an act.
Justification: To be aligned with Clause 44 of the Act and Clause 94(2)(q). The Food and Drug Administration, the most stringent Health Products authority in the world, places food, Drugs, Medical devices, radiation-emitting products, vaccines, blood, biologicals, animal and veterinary products, cosmetics, and tobacco products, as seen on their website. https://www.fda.gov/ Also European Medicines Agency https://www.ema.europa.eu/en/human-regulatory-overview. To be aligned with Clause 44 of the Act and Clause 94 Subsection 2 (q), CAP 241, Clause 46 (C).

Committee resolution: Not adopted. The classification under the Bill and the Health Act, Cap. 241 are sufficient. The other specifies will be set out in subsidiary legislation.

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENTS

Paragraph 1

In relation to the proposed definition of the term "healthcare services", all premises are in the **addendum 1.**Aligned and assign all healthcare professionals connected thereof and incidental to the Amendment of CAP 241 Section B, CAP 244, CAP 245 and any other act before the bill is enacted to an act.

Justification: To be aligned with Clause 44 of the Act and Clause 94(2)(q). The Food and Drug Administration, the most stringent Health Products authority in the world, places food, Drugs, Medical devices, radiation-emitting products, vaccines, blood, biologicals, animal and veterinary products, cosmetics, and tobacco products, as seen on their website. https://www.fda.gov/ Also European Medicines Agency https://www.ema.europa.eu/en/human-regulatory-overview. To be aligned with Clause 44 of the Act and Clause 94 (2 (q), CAP 241, Clause 46 Subsection C.

Committee resolution: Not adopted. The classification under the Bill and the Health Act, Cap. 241 are sufficient. The other specifies will be set out in subsidiary legislation.

Paragraph 19 and 20

Delete paragraph 19.

Justification: Section 23A proposed for deletion relates to the power of the Pharmacy and Poisons Board to register and close premises. Registration and licensing of pharmacy premises ought to be a preserve of the Pharmacy and Poisons Board in line with Kenya's ML3 goal.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 21
Delete paragraph 21.

Justification: Consider retaining the current section 44(1)(mb) which currently gives the Cabinet Secretary responsible for health in consultation with the Pharmacy and Poisons Board the power to make rules on the standards and practice of pharmacy. This role will still be undertaken by the Cabinet Secretary responsible for health under the Bill. The attainment of the ML3 status by Kenya is an ongoing process being undertaken by the Ministry in collaboration with the PPB. The proposed amendment is not only defective but also in breach of Kenya's commitment to international obligations under WHO.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

ADDITIONAL CONSEQUENTIAL AMENDMENTS

Paragraph 27,Part I of the Fourth Schedule to the Constitution; Health policy.
The Clause proposes the National Government to establish Health Policies in favour of the constitutional rights of every Kenyan. Focus should on the Cabinet secretary of Health establish and publish the Ministry organogram with directorates aligned to all regulatory bodies and Ministry divisions under each established directorate and secondments to other Ministries departments and agencies.

Justification: The Constitution justifies organization structures to ensure national government runs seamlessly.

Committee resolution: Not adopted. The clause as drafted is in order as it focuses on the policy aspects.

Paragraph 2,Part II of the Fourth Schedule to the Constitution; County health services,
The Clause proposes the county Government to establish Health services in favour of the constitutional rights of every Kenyan. Focus should on the CEC of Health establish and publish the Ministry organogram with directorates aligned to all regulatory bodies and Ministry divisions under each established directorate.

Justification: The Constitution justifies organization structures to ensure county government runs seamlessly.

Committee resolution: Not adopted. The clause as drafted is in order as it focuses on the policy aspects.

Social Protection Act, No. 12 of 2025
Clause 29 proposes Social Protection benefits. PSK Nairobi Branch proposes that inclusion of facilities offering healthcare services registered under this clause be included in this bill.

Justification: This is to ensure that healthcare provided under the Social Protection Act is uniform with this Bill.

Committee resolution: Not adopted. All healthcare services and benefits are covered under the Bill.

Persons with Disabilities Act No. 4 of 2025
Clause 24 proposes right to health for people with disability. Person with disability to include in the interpretation of a patient under clause 2.

Justification: Persons with Disabilities Act, No. 4 of 2025 in clause 2 defines a person with disability as someone who requires long term care. "persons with disabilities" includes persons with long term physical, mental, intellectual, developmental or sensory impairments, including visual, hearing or albinism, which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.

Committee resolution: Not adopted. The Persons with Disabilities Act, No. 4 of 2025 sufficiently addresses healthcare services even for persons with disability.

General Comments on the Bill

1. Article 43 of the Constitution provides for social and economic rights which include the right to the highest attainable standard of health including the right to health care services. The health function is devolved, with functions distributed between the National Government and County Governments in the Fourth Schedule. The National Government is tasked with formulation of the Health Policy while the County Governments are assigned the role of managing county health facilities and pharmacies, ambulance services and the promotion of primary health care.

2. The Health Act, Cap. 241, which seeks to implement the Constitutional provisions on health matters further stipulates that the National Government shall coordinate development of standards for quality health service delivery and promote the use of appropriate health technologies for improving the quality of healthcare.

3. International instruments that Kenya has ratified also speak to this issue and especially in line with health products and technologies and the practice of pharmacy. WHO recognizes health products and technologies as one of the key building blocks of a health system. For instance, the WHO's Global Benchmarking Tool (GBT) which defines nine core regulatory functions including licensing of premises and regulatory inspection, requires all medicine-handling facilities of member states (manufacturers, wholesalers and retail pharmacies) to be regulated by one regulatory body.

4. The GBT which classifies national regulatory systems into maturity levels, has classified Kenya at Maturity Level 2 which means Kenya has foundational regulatory structures in place. The aim is to elevate Kenya to ML3 status which means aligning Kenya's ability to independently regulate medical products in line with international good practices.

5. In line with this, the Pharmacy and Poisons Board in collaboration with the Ministry of Health has made great strides in driving reforms to align the regulatory framework with the WHO standards. This includes establishing quality management systems, digitization of licensing and enhancing post-marketing surveillance.

6. Attainment of ML3 status for Kenya would be a huge achievement as it would accelerate access to safe and effective medical products through faster approval processes, elevate public trust by ensuring quality and safety in health products and technologies and open up opportunities for mutual recognition arrangements and inclusion into the WHO Listed Authorities networks.

7. The Bill addresses some of the issues and challenges raised in health sector policies. It has made some progressive proposals, for instance, in *clause 18 of the Bill*, on patient safety and quality assurance measures, it states that every health facility shall adhere to the scope for healthcare providers employed or contracted by them. This aligns with the proposals around the anticipated Pharmacy Practice legislative framework.

8. However, some suggestions on how to improve the Bill include;- There is need to ensure that, in line with global good practice, regulation of the premises and practice of pharmacists is not separated. This is because the practice is linked to the product held within the premises that is to be dispensed to a patient. Furthermore, Kenya risks losing the ML3 pathway if licensing is split between the Pharmacy and Poisons Board and the proposed Quality Healthcare and Patient Safety Authority.

9. In the UK for example, the Medicines and Healthcare Products Regulatory Agency (MHRA), which is the equivalent of the Pharmacy and Poisons Board in Kenya, undertakes the registration and licensing of pharmacies in order to ensure that all pharmacies in the UK are legally compliant and meet standards for the safe handling and provision of medicines. The scope of this regulation entails regulating the pharmacy premises, the medicines they handle, and the sale of medicines, classifying them into legal categories like General Sales List (GSL) and Pharmacy (P). The process involves an initial inspection and approval, followed by applying for staff licensing and a final inspection and fee payment. Afterward, a mandatory licence to operate as a pharmacy is issued.

10. National Health Service/Care Quality Commission carries out accreditation whose purpose is to demonstrate a pharmacy's commitment to delivering continuous high-

quality patient care, setting high standards, and fostering continuous improvement within the National Health Service. It encompasses various aspects, such as accreditation of specific programmes for staff development or quality assurance of services like hygienic preparation of medicines within National Health Service facilities. This involves gathering evidence on whether requirements have been met for roles like training officers and adherence to quality standards, the outcome of which is a voluntary quality benchmark and a route to recognition for practitioners and services within the National Health Service.

11. In line with the above, the PSK urges the Committee to consider recognizing Pharmacy as a unique cadre based on how the healthcare service relating to pharmacy is offered across the world. Furthermore, PSK Nairobi proposes that registration and licensing of community pharmacies is left to the Pharmacy and Poisons Board or to be carried out jointly with the proposed Quality Healthcare and Patient Safety Authority(Authority). This will be integral in safeguarding Kenya's ML3 goal by preserving this integration.

12. Borrowing from the UK example, PSK Nairobi proposes that the Authority retains the role of accreditation of pharmacies in line with the standards and guidelines developed by the Cabinet Secretary and Director-General, respectively.

Committee resolution: The Committee noted the general comments.

40. DR. RICHARD MOGENI-CONSULTANT OBSTETRICIAN AND GYNAECOLOGIST, MASTERS IN BIOTECHNOLOGY OF HUMAN ASSISTED REPRODUCTION

Dr. Richard Mogeni-Consultant Obstetrician and Gynaecologist, Masters in the Biotechnology of Human Assisted Reproduction, submitted as follows;

a) Clause 6

Insert a new clause on Government Accountability: "The National and County Governments shall ensure adequate staffing, medicines, equipment, and infrastructure. Where government failures materially contribute to poor outcomes, the responsible entity shall be held accountable through reporting to Parliament and sanctions prescribed in regulations."

Justification: Government Accountability is Missing; The Bill places penalties on providers but not on government when shortages, stock-outs, or poor infrastructure directly cause preventable deaths.

Committee resolution: Not adopted. Government accountability is implied.

b) Clause 18

Replace clause 18(2) which has criminal penalties with: "A person who wilfully or recklessly causes harm to a patient by an act or omission amounting to gross negligence or criminal conduct shall be liable under the Penal Code and relevant professional disciplinary procedures." Non-compliance with administrative requirements shall attract corrective action plans, suspension of accreditation, or fines as may be prescribed."

Committee resolution: Adopted with amendments. To remove the penalty of imprisonment.

c) **Clause 20**

Insert the following new clause immediately after Clause 21:

"Clause 21: Confidentiality of Learning Systems
"Records from MPDSR, morbidity & mortality reviews, peer review sessions, or quality improvement forums shall be confidential and inadmissible in criminal or enforcement proceedings, except where independent evidence of wilful misconduct exists."

Justification: Lack of Protection for Learning Systems; The Bill is silent on confidentiality of MPDSR, morbidity & mortality reviews, or peer reporting. Without legal protection, clinicians will withdraw from these essential learning processes.

Committee resolution: Not adopted. This will set out in subsidiary legislation.

d) **Clause 22**

Replace Clause 22(4) on Accreditation and SHI Access with: "Access to the Social Health Insurance Fund shall be based on minimum safety standards. Facilities not meeting higher benchmarks shall be given phased compliance plans and technical support before suspension or withdrawal is considered."

Justification: Linking Financing to Accreditation Scores-Clauses 23(4) and 68–70 tie SHI access to quality benchmarks. Facilities in resource-poor counties will be penalized for government failures beyond their control. Patients may lose access to care. There is also a lack of clarity on which accreditation benchmarks are used and how they are measured. If these are to influence financing, it is critical that the benchmarks align with nationally and internationally accepted quality standards (e.g., KEBS, JCI, ISQua), and that facilities are assessed through transparent, verifiable methodologies.

Committee resolution: Not adopted. The clause is in order as drafted as it in line with the social health insurance law.

e) **clause 27**

The Authority shall act primarily as a supportive accreditation and capacity-building body.

f) **Clause 29**

The Board of the Authority shall include representatives from regulatory councils and at least three specialist professional societies."

Committee resolution: Adopted with amendments. This will ensure that the interests of statutory regulatory bodies are well take into account by the proposed Authority.

Part IV Clauses 67–69 on penalties,

Proposed to introduce the provision: "Failure to meet quality targets shall first attract supportive interventions (improvement plans, technical support, mentoring). Penalties may apply only where a facility persistently refuses corrective measures."

Committee resolution: Not Adopted. The penalties are necessary for ensuring compliance.

g) **Clause 70**

Clause 73-80 on inspection powers, proposes that "Inspections shall be conducted by teams including clinical experts. Reports shall distinguish between failures caused by government under-resourcing and those attributable to facility management. Inspections and quality ratings shall be based on standardized metrics developed in collaboration with KEBS, ISQua-aligned bodies, and specialist societies."

Committee resolution: Not Adopted. This will be set out in subsidiary legislation.

41. **DR. KIPRUTO CHESANG** submitted as follows;

(a) In relation to clause 2, the definition of the term "Adverse Event" is ambiguous due to its broad use of "medical management." This term includes appropriate care as well as errors, thereby failing to differentiate between adverse events and medical errors, which complicates accountability, reporting, and liability. The rate of medical errors distinguishes quality healthcare from substandard care. He suggested adoption of the following definitions:

- Adverse Event- is an unintended injury or complication that results from medical care, which may occur despite appropriate medical management and is not solely attributable to the underlying disease process.
- Medical Error- is a preventable mistake in the provision of healthcare that may lead to an adverse event. This includes errors in diagnosis, treatment, medication administration, or communication among healthcare providers.

Clarification is critical to avoid misinterpretation, especially in complex interventions such as mass vaccination campaigns, where some adverse effects are not preventable but foreseeable. Additionally, these proposed definitions are consistent with the World Health Organization's ICD-11 Framework for Patient Safety, which explicitly differentiates adverse events from preventable medical errors. Codifying this distinction would harmonize national legislation with internationally accepted standards, improve reporting accuracy, and strengthen accountability mechanisms.

Committee resolution: Not Adopted. The definition is in order as is.

(b) Amend clause 3(c) to "guarantee patient rights, satisfaction, and safety." Patient satisfaction is arguably the most important factor in quality of care.

Committee resolution: Not Adopted. This is already provided for under clause 3(a).

(c) In relation to clause 5. Assigning all responsibility for policy and guideline formulation to the Cabinet Secretary without requiring structured expert input or no mandatory technical advisory mechanisms is problematic. Clause 5 should explicitly indicate that the Cabinet Secretary shall act "based on recommendations from the Director General of Health or any other lawful technical advisory mechanism."

Committee resolution: Not Adopted. The Cabinet Secretary is responsible for policy. The Bill has set out instances where the recommendation of the Director General of Health is required.

(d) In relation to clause 6, there is need to clarify county government roles. While counties collect data and oversee quality improvements under clause (6(f) and 6(i)),

there is no specified mechanism for coordination with the national level clause(5(c)). How will conflicts be resolved when the national and county governments differ, for instance in closing health facilities (clause 5(e) vs. clause 6(h))? The Bill should establish a National–County Joint Quality Coordination Committee or require the national government to consult the Council of Governors on quality-of-care matters. Clause 6(a) currently mandates strict adherence to national protocols. This may unintentionally constrain healthcare providers during emergencies or industrial labour strikes. Revise clause 6(a) to "implement the national government policies, guidelines, protocols, and standards prescribed under this Act and other relevant laws, while allowing for flexibility in emergency situations to ensure that healthcare providers can take necessary actions that prioritize patient safety and well-being without fear of conflicting with this law." An example of this can be as simple as inserting an infusion line. Although this may be restricted to medical and clinical officers, during an emergency such as a massive accident, this may as well be done by nurses or even medical students. Furthermore this flexibility is consistent with the WHO Emergency Care Systems Framework (2019), which emphasizes adaptable care roles and context-appropriate decision-making in emergency and mass-casualty situations to ensure timely, life-saving interventions.

Committee resolution: Not Adopted. The county government functions are aligned with the Constitution.

(e) The requirement in Clause 6(g) for county governments to establish digital reporting systems integrated with the national Comprehensive Integrated Health Information System under the Digital Health Act is well-intentioned but may face harmonization challenges due to differing interpretations and capacities across counties.

Committee resolution: Not Adopted. This is already provided for under the Digital Health Act, 2023.

(f) Clause 11 rightly upholds patients' rights but overly emphasizes complaint resolution, which could promote defensiveness in staff. More balance is needed to support a positive patient-provider relationship. Of particular importance is for this section introduce a legal distinction between "complaints" and "feedback." While complaints involve alleged violations requiring investigation and redress, feedback should be recognized as a nonpunitive, quality-improvement mechanism. Clarifying this distinction would prevent unnecessary defensiveness by healthcare providers and promote a culture of continuous improvement. Clause 11 should be amended as follows:

- Subclause 2(d): "Provide feedback on their healthcare experience through structured processes, such as exit interviews, feedback loops, and analysis to measure overall patient satisfaction and identify areas for improvement."
- Subclause (3): "A health facility shall provide a mechanism for patients to lodge complaints and offer feedback."
- Subclause (4): "The Authority shall issue a standardized template of the internal dispute resolution mechanism for health facilities, updated every two years, to promote efficient redress of complaints and to incorporate patient feedback into quality improvement initiatives."
- New subclause (5): "Health facilities shall regularly analyze feedback from patients to enhance service delivery and ensure that patient satisfaction is considered in the development of healthcare practices."

Committee resolution: Not Adopted. This will be addressed in subsidiary legislation.

(g) Clause17 fails to address critical and well-recognized barriers faced by women, adolescents, and other vulnerable groups in accessing care. He recommended adding the following provisions, consistent with WHO standards on respectful maternity care:

- Subclause (3): "Recognizing the unique challenges faced by specific populations, particularly pregnant women seeking maternal delivery services , adolescents and young women seeking reproductive health services such as family planning, and other vulnerable groups, healthcare providers shall ensure that these groups receive care that is free from coercion, stigma and abuse."
- Subclause (4): "Healthcare facilities shall implement training programs for staff to promote respectful communication and to eliminate the use of abusive or judgmental language."
- Subclause (5): "Healthcare facilities shall establish clear protocols for reporting and addressing instances of abusive or judgmental language or behavior, including through structured exit interviews.

These recommendation aligns with United Kingdom NICE Quality Standards, which distinguish general patient feedback—used for quality improvement—from formal complaints requiring investigation.

Committee resolution: Not Adopted. This will be addressed in subsidiary legislation.

(h) Amend clause 22(1) as follows:

- (c) Report adverse medical events, medical errors, and any other concerning public health incidents to the Authority through the Comprehensive Integrated Health Information System established under the Digital Health Act."
- "(d) Implement procedures for detecting, analyzing and reducing health risks, medical errors, and adverse events."

Committee resolution: Not Adopted. This is provided for under the Digital Health Act, 2023 and the Pharmacy and Poisons Act, Cap. 244.

(i) Amend clause 24(b) to "Provide periodic training on patient safety, clinical guidelines, and any other relevant topics necessary for quality improvement."

Committee resolution: Not Adopted. This is already provided for under the Bill.

(j) Amend clause 29(2)(g) to take account international governance standards (ISO, OECD) to "receive gifts, grants, donations or endowments made to the Authority or any other monies in respect of the Authority, while ensuring that these do not create any real or perceived conflicts of interest and make legitimate disbursements therefrom in accordance with the provisions of this Act."

Committee resolution: Not Adopted. This is already addressed under the clause 29 and the First Schedule.

(k) In relation to Clause 54, categorizing health facilities from Levels 2 to 6 is straightforward; however, this approach may overlook the operational complexity within the health sector. While the current framework appropriately addresses organizational tiers, it does not adequately account for stand-alone service-type differentiation. Maintaining the levels is important, but the Act should also recognize and categorize specialized health facilities to ensure that services, specific protocols and standards are effectively implemented. Introduce a new paragraph (b) to immediately come after paragraph (a) and the current paragraph (b) to move to paragraph (c). The new paragraph (b) to state "categorize specialized health facilities, including standalone pharmacies, laboratories, radiological services, and specialized clinics such as renal, cancer, and reproductive health, as outlined in the regulations of this Act;"

Committee resolution: Not Adopted. The specifics will be addressed in subsidiary legislation.

(l) In relation to clause 61, the Bill's current criteria are static (a–g). Medicine is a dynamic field, constantly evolving with new knowledge and skills. To ensure that this law remains relevant amidst such advancements, amend to introduce a new subclause "(h) Conformity to any additional medical standards as deemed appropriate by the Cabinet Secretary, based on the recommendations of the Director General of Health."

Committee resolution: Not Adopted. This will be accommodated under clause 59(h) which gives room for discretion.

(m) The level of detail in clause 68 is better suited for regulations or schedules and should be removed from the main body of the Act. Acts normally set frameworks; details belong in subsidiary legislation.

Committee resolution: Not Adopted. This is necessary for clarity and uniformity.

(n) Clause 85(4)(c) unjustifiably excludes healthcare professionals from serving on the Tribunal, despite the valuable expertise they bring to resolving healthcare-related disputes. Any qualified healthcare professional in good standing should be eligible for appointment, provided that established conflict-of-interest safeguards—already outlined in the First Schedule, in subclause (3) – are strictly observed. Alternatively, the Act could permit the appointment of non-practicing or retired health professionals, thereby maintaining neutrality while ensuring that the Tribunal benefits from essential clinical and operational expertise.

Committee resolution: Adopted with amendments. The Health Care Tribunal requires a skills mix that includes healthcare professionals for purposes of ensuring fairness and sound judgement in its processes.

(o) In relation to the Second Schedule (s. 102), the definitions of the terms "healthcare services" and "health facility" should be re-evaluated. The current draft omits post-mortem services, which are critical for diagnosis and should be included. Other end-

of-life services may require separate definition if the intent is to include such service that go beyond living individuals.
Committee resolution: Adopted with amendments. The definition of the term "healthcare provider" is more comprehensive as it includes a healthcare professional providing healthcare services.

(p) KENAS under the Kenya Accreditation Service Act, 2019 is mandated to accredit laboratory services, is omitted. Its exclusion may lead to jurisdictional confusion or duplication. KENAS should be explicitly referenced for clarity and complementarity.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

(q) Dr. Chesang proposed the following additions;

- excessive centralization to the position of the Cabinet Secretary: The Act places substantial unchecked authority in the Cabinet Secretary, with inconsistencies regarding the need for expert advice (sporadic references to the Director-Genera). Drawing from international examples (e.g., USA and UK), such centralization risks undermining scientific integrity. All such powers should be exercised only upon the advice of relevant lawful expert bodies under the Director General of Health. The Director General of Health is a medical doctor and is subject to disciplinary action by the Kenya Medical Practitioners and Dentists Council for any professional misconduct, whether through omission or commission. On the contrary, there is no recourse to correct "professional misconduct" of a Cabinet Secretary.
- absence of medical ethics: The omission of "medical ethics" is a major gap. Medicine is an ethical as well as a scientific profession, governed by principles such as beneficence, nonmaleficence, autonomy, and confidentiality.
- Under clause 4, insert "medical ethics" as a guiding principle.
- Under clause 24(6) and 28(1), require mandatory training in medical ethics as part of quality improvement and patient safety initiatives.

Committee resolution: Not adopted. Issues of ethics need not be addressed in legislation. The Cabinet Secretary is responsible for policy matters.

42. **MR. GEORGE OTIENO AGAL** submitted as follows;

a) **Clause 9**

On accountability of health workers, the Bill requires healthcare providers to follow ethical and professional standards. Recommends clear penalties for negligence or malpractice, alongside mechanisms to protect whistleblowers who report unsafe practices.

Committee resolution: The Committee noted the comment.

b) **Clause 16**

On complaints and redress mechanisms, the Bill provides for complaints handling. Recommends a toll-free hotline and a digital reporting system to make it easy for citizens to raise concerns.

Committee resolution: The Committee noted the comment.

c) **Clause 17**

On patient rights, the Bill rightly emphasizes the right of patients to dignity, safety, and information. Recommends that the Authority develops a patient rights charter to be displayed in all facilities for public awareness.

Committee resolution: The Committee noted the comment.

d) **Clause 18**

On patient safety systems, reporting and learning from medical errors is a progressive step. Anonymized data on patient safety incidents be published annually to encourage system-wide learning accountability.

Committee resolution: The Committee noted the comment.

e) **Clause 76**

Recommends mandatory public reporting of inspection results so that citizens can make informed choices on where to seek care. Regular inspection is vital to ensure compliance.

Committee resolution: The Committee noted the comment.

f) **Clause 87**

On resourcing the Authority, for the Authority to be effective, it must be adequately funded and staffed. Recommends that Parliament ensures budgetary allocation is ringfenced for patient safety and quality improvement.

Committee resolution: The Committee noted the comment.

GENERAL COMMENTS ON THE BILL

1. Strongly supports the Bill because it establishes a framework for ensuring safe, high-quality healthcare services for all Kenyans, provides for the creation of a Quality Healthcare and Patient Safety Authority to oversee standards, ensures that health facilities are licensed, accredited, and regularly monitored, and places responsibility on both the national and county governments to guarantee quality healthcare.

2. The Bill is a timely and necessary piece of legislation that will significantly improve health outcomes in Kenya. By embedding patient safety and quality as legal requirements, it ensures that Kenyans will be protected from preventive harm and can access health care that is safe, dignified, and of high standard. Urged the National Assembly to consider the recommendations to strengthen the Bill further.

Committee resolution: The Committee noted the general comments by Mr. Agal.

43. **THE KENYA HEALTH PROFESSIONS OVERSIGHT AUTHORITY (KHPOA)**

The Kenya Health Professions Oversight Authority (KHPOA) submitted as follows;

a) **Clause 8**

Amend clause 8(2)(a) to state that: "Every health facility shall – (a) Implement health care and professional standards set out in this Act and other relevant laws.

Justification: There is no mention of health professionals and it excludes reference to professional standards issued by statutory regulatory bodies. Health care facilities are subject to both health care standards and professional standards enforced under establishing legislation by respective regulatory authorities.

Committee resolution: Not adopted. This is already provided for within the Bill.

b) **Clause 19**

Amend clause 19(2) to: "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 fifty million shillings or to imprisonment for a term not exceeding ten years, or both".

Justification: The clause refers to a person who fails to comply and yet the main section is referring to a "health facility.

Committee resolution: Adopted with amendments. The Bill amended to reduce the find and remove the aspect if imprisonment.

c) **Clause 28**

i. Amend clause 28(e) to read: "(e) inspect health facilities for compliance with set norms and standards for quality health care."

Justification Clause 28(d) needs to be qualified further.

Committee resolution: Not adopted. This is already provided for within the Bill.

ii. Amend clause 28(g) to read: "Establish and implement a system of certification based on compliance levels of quality of health care."

Justification: The use of the term "accreditation" is likely to cause concerns as the scope is unclear and it may conflict with functions of other agencies providing accreditation services especially KENAS.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

iii. Delete section 28(j).

Justification: The use of the word "accredit" conflicts with the regulatory function of health professional regulatory bodies mandated under respective statutes to set internship training, registration and practice standards, certify designated health facilities and approve internship programs. Further, the role of KHPOA is to provide oversight to ensure compliance to these set standards by regulatory bodies on internship programs. Therefore, the proposed clause risks creating overlaps and jurisdictional tension between the proposed Authority, health professional regulators and KHPOA.

Committee resolution: Adopted with amendments. The Authority will accredit for purposes of quality healthcare. Health professional regulatory bodies to retain the function of inspecting and accrediting health facilities for purposes of internship and training.

d) Clause 73(2)(b)

Amend the clause to clarify that the new Authority assesses facility adherence to quality norms, while individual professional competency remains under the relevant Boards overseen by KHPOA. The Bill to define the term "Competency".

Justification: This bypasses the specialized regulatory functions (Medical, Nursing, etc.) who are the legal custodians of health professional competency standards.

Committee resolution: The clause as drafted is in order. Issues of competency shall remain the function of health regulatory bodies.

e) Clause 80; PART IV

Amend part IV to explicitly define the function of the tribunal and especially to read as follows :"The Health Care Tribunal shall receive and resolve complaints which remain unresolved or unsatisfactorily addressed by regulatory bodies, health facilities or the Kenya Health Professions Oversight Authority. The tribunal shall also serve as an appellate body for decisions made by these entities in the exercise of complaints resolution mandates or disciplinary processes.

Justification: The proposed Tribunal under Part IV is a positive step toward strengthening accountability and access to justice in the health sector. However, the functions of the tribunal are not clearly defined or provided for, creating ambiguity in its role and potential for overlap and/or conflict with KHPOA and regulatory bodies mandated to handle or process complaints from dissatisfied patients, professionals and regulatory bodies. Complaints involving health professionals are handled by respective health facilities and regulatory bodies while KHPOA coordinates handling and reporting, including resolving of multi-disciplinary complaints.

Committee resolution: Adopted with amendments. The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

f) Clause 84(3)

Amend Clause 84(3) so that the proposed Tribunal has original jurisdiction only over disputes between health facilities and patients, and not over healthcare providers or regulatory bodies.

Dispute handling should follow this pathway:

- Patient vs. Facility: Primarily complaint addressed at the facility level, with escalation to the Tribunal if patient or aggrieved party dissatisfied or complaint is unresolved.
- Patient vs. Health Professional: Complaint is handled first by the relevant professional regulatory body; if no resolution or patient dissatisfied with decisions of the body , then escalated to KHPOA; and only then to the Tribunal as a last-resort appellate mechanism.
- Multidisciplinary disputes among different cadres of health professionals: Managed by KHPOA, with the Tribunal serving solely as the final appellate authority, not the first point of resolution.

This ensures the Tribunal focuses on escalated complaints/ disputes, while KHPOA and regulatory bodies maintain authority over professional standards and inter-cadre issues.

Justification: The proposed function of the Tribunal risks diluting the roles of professional regulatory bodies & KHPOA in handling complaints. It should instead be confined to handling disputes or complaints by patients dissatisfied with decisions of health facilities or regulatory bodies.

Committee resolution: Adopted. The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

g) **Clause 93**

Insert an additional provision requiring the Cabinet Secretary to "Make regulations providing for norms and standards for rehabilitative services".
Justification: Norms and standards of rehabilitative services have been left out and yet they are very crucial in contributing to quality of care, especially reducing the average length of stay (ALS) of patients in hospitals.

Committee resolution: Not adopted. Healthcare services include rehabilitative services.

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENTS

Paragraph 1

Broaden the definition of the term "health facility" to expressly include all forms of clinical set ups or premises providing health care services, including standalone clinics, mobile and outreach units, telemedicine centers and other emerging facility models, with multi-disciplinary professionals.

Justification: The current definition is narrow in scope and does not clearly include standalone clinics, mobile units like ambulances or telemedicine platforms which are increasingly part of modern health care delivery system.

Committee resolution: Not adopted. The proposed definition is in order. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 5

Restore Section 48(b), (c) and (d) of the Health Act, but with Amendments. KHPOA should retain its role in promoting and regulating collaboration between statutory regulatory bodies, because the Authority is mandated to Oversight all health regulatory bodies , and promote inter-professional linkages needed for integrated health system (holistic regulation). KHPOA should continue to coordinate joint assessment, focusing on compliance with professional standards(training, licensure & ethical practices), while the proposed Authority concentrates on health facility-level assessments. In relation to section 48(d) on complaints handling, this function should be retained to enable KHPOA, in collaboration with health regulatory boards and councils, to receive and resolve complaints, with clear delineation of scope as follows:

- Professional complaints (e.g., misconduct, negligence, breach of professional standards) should be handled by respective regulatory bodies and KHPOA.
- Health Facility-related complaints (e.g., poor sanitation, infrastructure deficiencies, non-compliance with facility standards) to fall under the mandate of the proposed Authority.

Justification: This removes powers of KHPOA to coordinate joint inspections, manage inter-professional liaison, and resolve complaints.

i. Retain section 48(1)(c) with clarification:"(c) coordinate joint assessment of health professionals within health facilities in collaboration with the respective health regulatory bodies, focusing on matters relating to the availability, staffing, placement, deployment, training, practice, professional conduct, and discipline of health professionals."

Justification: The proposed deletion of KHPOA's coordination role in joint inspections under Section 48(c) of the Health Act, 2017, undermines oversight of critical aspects such as the availability, staffing, placement, deployment, professional conduct, training, and discipline of health professionals.

Committee resolution: Adopted with amendment. The clause amended to limit the role of the Kenya Health Professionals Oversight Authority to the regulation of healthcare professionals.

ii. Retain section 48(1)(d) with clarification: "KHPOA shall receive and facilitate resolution of complaints lodged from patients, aggrieved parties and disputes from regulatory bodies".

Justification: The proposed deletion of Section 48 (d) automatically removes KHPOA's mandate of coordinating resolutions of complaints against health professionals from patients, aggrieved parties and regulatory bodies.

Committee resolution: Adopted with amendment. The clause amended to limit the role of the Kenya Health Professionals Oversight Authority to the regulation of healthcare professionals.

iii. A four-tiered level of handling complaints should be established to enhance efficiency, accountability and promote patient and health professional rights.

Justification: KHPOA provides oversight in resolution of complaints handled by regulatory bodies and ensures protection of patient and promotion of professional rights. Health facilities and regulatory bodies handle primary complaints while KHPOA facilitates resolution of multidisciplinary complaints, including disputes between health regulatory bodies.

Committee resolution: Adopted with amendment. The clause amended to limit the role of the Kenya Health Professionals Oversight Authority to the regulation of healthcare professionals.

Paragraph 6

To maintain system-wide oversight, amend the proposed amendment to Section 60 to retain the obligation for KHPOA and regulatory bodies to read "inspect, monitor and evaluate the standard of performance of all health professionals engaged in the health sector, both public and private".

Justification: This removes the critical inspection function, by regulatory boards and councils to verify the competence, performance, and compliance of health professionals in practice(removes source of revenue).

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals

Paragraph 9

To preserve KHPOA and regulatory oversight of professionals, amend the proposed amendment to Section 91(1)(a) of the Health Act to clarify that while the Quality Health Care and Patient Safety Authority inspects health institutions, KHPOA together with the professional regulatory boards and councils retains statutory authority to inspect or assess health professionals.

Justification: The amendment removes KHPOA and professional regulatory boards and councils from respective roles in assessment for compliance of health professionals to conduct, licensure & ethical practices), but also removes source of revenue.

Committee resolution: Adopted. The Kenya Health Professionals Oversight Authority and other regulatory bodies will undertake inspection as regards the regulation of healthcare professionals.

GENERAL COMMENTS BY KHPOA

The Bill is a critical step in health sector reforms. It Promotes:

- ✓ Provision of quality patient-centered care;
- ✓ Accountability of health facilities;
- ✓ Standardization of healthcare delivery; and
- ✓ Attempts to introduce separation of regulation of Health services and Health Professionals .

The Bill introduces a much-needed focus on the Regulation of Service (facility standards, equipment, and environment). The Authority notes that that the Bill will effectively address the longstanding regulatory challenges related to the separation of regulation of service from the regulation of professionals and health products.

The development of the Bill is in line with the Constitution of Kenya, 2010 and the Health Act, 2017.This is a major milestone towards ensuring citizens are able to access the highest attainable standards of health through delivery of patient centered quality care. Further, the bill proposed will ensure compliance to set standards and social accountability on the part of the health facility.

The specific recommendations seek to align the Bill with existing legal frameworks, eliminate duplication and preserve the distinct regulatory role of KHPOA and health professional regulatory bodies. A harmonized approach will ensure effective service delivery, legal clarity and accountability at both facility and health practitioners' level.

Effective healthcare systems depend on two distinct but complementary areas of regulation needed to deliver quality health care:

- the regulation of health facilities and quality of care; and
- the regulation of the integrity, conduct, competence & ethical practices of health professionals.

KHPOA supports the Bill but strongly urges the retention of its core oversight functions, with targeted amendments to align with the proposed framework. The Bill should not be designed to dilute or seen to introduce overlaps with existing regulatory and oversight agencies.

Committee resolution: The Committee noted the general comments by KHPOA.

44. **KAPI-INDUSTRY ALLIANCE OF HEALTH PRODUCTS AND TECHNOLOGIES** submitted as follows;

a) **Clause 14**

Replace the statement "Every healthcare provider shall prescribe, administer, and monitor treatment" in clause 14(2) with "Every healthcare provider, operating within their authorized scope of practice, shall:"

Justification: The original phrasing in the Bill is broad and unspecific. It implies that all categories of healthcare providers— including those not legally authorized to prescribe or administer treatment—would be permitted to do so. The Authority to prescribe, administer, and monitor treatment varies from one healthcare provider to the other and depends on the licensure as issued by the regulatory bodies. The recommended statement ensures that only authorized scopes are permitted.

Committee resolution: Not adopted. Issues of scope of practice addressed in the Bill

b) **Clause 29**

Under clause 29(1), healthcare Providers are underrepresented on the Board of Directors of the Authority. Members of the Board should mirror the constitution of other healthcare regulatory authority boards. Refer to the constitution of KMPDC and PPB.

Justification: Lack of representation of healthcare providers in the composition of the Board of Directors of the Authority. A board with strong professional representation can provide informed oversight and advocacy.

Committee resolution: Adopted with amendment. The clause amended so that the interests of statutory regulatory bodies are well take into account by the proposed Authority.

c) **Clause 42**

Delete clause 42.

Justification: There should not be an overlap of functions with other healthcare regulatory bodies - KMPDC, PPB, Nursing Council, Clinical Officers Council, and others. Clause 42 outlines the functions of a healthcare authority. Clause 42 should be governed by the existing regulatory authority that is - KMPDC, PPB, Nursing Council etc.

Committee resolution: Not adopted. The Bill proposes to separate the regulation of health facilities from that of healthcare professionals.

d) **Clause 48**

In clause 48(1), have a unified annual license to avoid multiple licensing by different authorities.

Justification: A unified license would simplify compliance for healthcare providers and facilities. A unified system would help reduce financial strain

Committee resolution: Noted. That is the essence of the Bill by separating the regulation of health facilities from that of healthcare professionals.

e) **Clause 87**

Part VIII

Avoid duplication of roles and functions of existing health regulatory bodies – KMPDC, PPB, Nursing Council, etc.

Justification: There is duplication of roles which not only introduces ambiguity in enforcement of standards but also risks creating loopholes for noncompliance.

Committee resolution: Noted. That is the essence of the Bill by separating the regulation of health facilities from that of healthcare professionals.

f) **Clause 93**

Delete clause 96 (2)(h) and (l) and maintain status quo in which the Pharmacy and Poisons Board, as currently authorized by CAP 244 continues to regulate these roles.

Justification: There's no clarity on the role on the pharmacies' standards, standards of alternative medicine and traditional medicine by the Board and PPB. The Authority should allow the PPB with its established organization capacity and structures to regulate pharmacy practice and minimize exposure of patients to harm that will happen should this role be stripped from PPB.

Committee resolution: Noted. That is the essence of the Bill by separating the regulation of health facilities from that of healthcare professionals.

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENTS

Paragraph 1

Replace the definition of 'health care provider' and replace with - Heath care provider is a person duly qualified and licensed to provide health care services.

Justification: The revised definition ensures that only individuals who are formally trained, certified, and licensed by recognized regulatory bodies are considered healthcare providers.

Committee resolution: Adopted with amendment. The definition of the term "healthcare provider" is more comprehensive as it includes a healthcare professional providing healthcare services.

Paragraph 14

i. Delete paragraph 14(a).

Justification: No deletion of paragraph (j). Deletion of this section will create a vacuum in regulation of pharmacy practice in Kenya. In the interim, there's going to be a vacuum which will introduce the market to uncertainties. This will also create a risk for patients, exposing them to harm. In addition, PPB already has the structures, institutional memory and capacity in this area. Therefore, stripping the Board of this power will lead to institutional capacity and memory loss.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

ii. Delete paragraph 14(b).*(Section 3B of CAP 244- Subsection 2 - deleting paragraph (i))*

Justification: No deletion of paragraph (i); maintain status quo of Cap. 244. Deletion of this section will strip PPB powers in regulating manufacturing, storage, distribution and even post marketing surveillance of pharmaceuticals in Kenya. This will not only impact quality of the products and pharmacy care but also hinder PPB from achieving Maturity Level 3 and all the benefits this has for manufacturing ambitions for Kenya.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

iii. Section 3B of CAP 244- Subsection 2 – deleting paragraph (f).

Justification: No deletion of paragraph (f); maintain status quo of CAP 244; Deleting of this section would mean that there's no longer an authorized register of medicines in Kenya. This will be detrimental to quality health, pharmaceutical care and will open up the market to unregulated products.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 18
Delete paragraph 18.

Justification: Don't repeal section 20. Maintain status quo in the current CAP 244. Repealing section 20 will interfere with the regulation of pharmacy practice in Kenya.

Committee resolution: Adopted. Pharmacy professionals engaged in professional practice would still be required to display their name and registration certificate.

Paragraph 19
Delete paragraph 19.

Justification: No repeal of Section 23 of Cap 244. Deletion of this section will take away the gains already made in combating illicit trade. It will create a vacuum that will open the market to unregistered and unregulated premises which will pose a risk to patients and result in the supply of illegitimate pharmaceutical products.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 20
Delete paragraph 20.

Justification: No repeal of Section 23A of Cap 244. Repealing of this section would mean that any unlicensed or uncompliant premise will continue to operate because PPB will no longer have the power to close that premise.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 21

In agreement with the deletion of paragraph (m) of Subsection 1 but recommends maintaining status quo for all the remaining paragraphs in Subsection 1.

Justification: Any other deletion in subsection 1 will affect the regulation of pharmacy practice and health products technologies in Kenya. This will not only impact quality of the products and pharmacy care but also hinder PPB from achieving Maturity Level 3 and all the benefits this has for manufacturing ambitions for Kenya.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

GENERAL COMMENTS ON THE BILL

- Maintaining the roles of other regulatory agencies in the health sector to avoid creating a vacuum and confusion in the industry that would expose patients to harm.
- Proposed granting PPB more control as opposed to reducing its control, as this goes against the spirit of achieving WHO Maturity Level 3.
- Powers of the Board of the Authority and the Cabinet Secretary should be clearly defined to avoid overlapping of functions with the already established regulatory agencies, authorities, and boards

Committee resolution: The Committee noted the general comments by KAPI.

45. THE KENYA MEDICAL PRACTITIONERS AND DENTISTS' COUNCIL (KMPDC)

The Kenya Medical Practitioners and Dentists Council submitted as follow;

a) Delete clause 28(j).

Justification: Internship forms part of the continuum of the regulation of the training of medical and dental students. By dint of this provision, KMPDC will not be able to effectively ascertain the quality of internship training for medical, dental and community oral health practitioners. The Council may consider administering a post-internship examination/pre-registration examination.

Justification: Adopted. Health professional regulatory bodies to retain the function of inspecting and accrediting health facilities for purposes of internship and training.

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENTS

Paragraph 27

Paragraph 27(b) amending Section 2 of the Medical Practitioners and Dentists Act be amended as follows—

(b) in the definition of the term "private practitioner" by deleting the expression "as either a medical practitioner or a dentist who is also licensed under section 15 to practise" and substituting therefor the words "who practices".

Justification: Private practice is centered around the practice of the medical, dental or community oral health practitioner. This should be left to KMPDC to regulate the private practice of medicine, dentistry and community oral health.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 28

Paragraph 28(a), that seeks to amend Section 4 of the Medical Practitioners and Dentists Act, be deleted.

Justification: Do not delete Section 4(f) from Cap. 253. Internship forms part of the continuum of the regulation of the training of medical and dental students. The Bill proposes removing KMPDC's role in inspecting and accrediting facilities for internship and training. KMPDC states that internship is part of the training continuum and should remain under its regulation. This is so that KMPDC can ascertain the quality and level of internship training prior to their registration and licensing as medical, dental and community oral health practitioners. By dint of this provision, KMPDC will not be able to effectively ascertain the quality of internship training for medical, dental and community oral health practitioners. The Council may consider administering a post-internship examination/pre-registration examination.

Committee resolution: Adopted. The Kenya Medical Practitioners and Dentists Council needs to retain the power to inspect and accredit new and existing institutions for medical and dental internship training in Kenya as the same relates to the regulation of the professional practice.

Paragraph 29

Paragraph 29 be deleted.

Justification: Do not delete the word "inspections" from Section 4A of CAP 253. This is also to allow KMPDC to inspect teaching hospitals (as part of the training), internship training centers and post-graduate collegiate centers. The Bill removes the word "inspections" from the Inspections, Licensing, Finance and General-Purpose Committee. KMPDC along with its sister regulatory bodies within the East African Community carry out inspection of medical and dental schools in fulfillment of the EAC Treaty and the EAC Common Market protocol provisions on the free movement of goods and professional services across the region. As per the Mutual Recognition Agreement, KMPDC is the competent authority in Kenya to implement the reciprocal recognition provisions.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 30

Section 5(3)(h) should not be deleted from Cap. 253

Justification: The Bill deletes provisions on KMPDC's role in regulating training. This is to cater for KMPDC to regulate the training of medical and dental students as provided for in the EAC Mutual Recognition Agreement. To allow KMPDC to regulate the training of medical and dental interns due to the fact that Internship forms part of the continuum of training of a practitioner to be.

Committee resolution: Adopted with amendments. The Kenya Medical Practitioners and Dentists Council needs to maintain a register of approved internship training centres as the same relates to the regulation of the professional practice..

Paragraph 35.
Section 17 of Cap. 253 should not be repealed, but should be amended to read as follows:

"**17. No fees recoverable unless person licensed under section 14** No person shall be entitled to recover a charge for medical or surgical advice or attendance, or for the performance of an operation as a medical practitioner or dentist, or for medicine which he has prescribed and supplied as a medical practitioner or dentist, unless he is at the time appropriately licensed under section 14."

Justification: This focuses on the recovery of fees by a practitioner only if he is licensed.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

ADDITIONAL CONSEQUENTIAL AMENDMENTS

Section 26 of the Medical Practitioners and Dentists Act
Introduce the following consequential amendment—

"Section 26 of the Medical Practitioners and Dentists Act is amended by adding subsection (5) that reads as follows; "(5) That the staff from KMPDC who handle matters pertaining to regulation of health facilities, who may be affected, be considered for transition to the Quality Healthcare and Patient Safety Authority within their existing terms and conditions."

Justification: This is so that the staff currently handling the function of registration, licensing, inspection and disciplinary matters of health facilities will not have any loss occasioned by the transfer to function. It is the Council's request that the staff from KMPDC who handle matters pertaining to regulation of health facilities, who may be affected, be considered for transition to the Quality Healthcare and Patient Safety Authority within their existing terms and conditions.

Committee resolution. Adopted with amendment. The staff currently handling the function of registration, licensing, inspection and disciplinary matters of health facilities will move to the Authority with their institutional memory and expertise.

GENERAL COMMENTS ON THE BILL

KMPDC's submission is intended to support a clear and consistent legislative approach to healthcare regulation in Kenya. The Council's recommendations focus on proposed amendments that touch on critical areas such as the regulation of internship training, inspection of medical and dental schools, licensing of practitioners, and enforcement mechanisms. KMPDC notes that some of the proposed changes could affect its ability to effectively discharge its mandate, particularly with regard to training oversight and compliance with regional obligations under the East African Community frameworks.

Committee resolution: The Committee noted the general comments by KMPDC.

46. THE PHARMACY AND POISONS BOARD (PPB)

The Pharmacy and Poisons Board (PPB) submitted as follows;

SECOND SCHEDULE- CONSEQUENTIAL AMENDMENTS
Paragraph 14

i. Delete paragraph 14(a).

Justification: The need for the PPB to inspect and license pharmacies including those in hospitals and clinics is to ensure compliance. The enforcement of both standards and requirement ensure there is synergy in seeking to ensure maintenance of high quality standards in practice of pharmacy. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

ii. Delete paragraph 14(b).

Justification: The justification in having the Board to approve and license the premises for the pharmacist and pharmaceutical technologist also ensures synergy in enforcement of standards. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 18
Delete paragraph 18.

Justification: The need for display of registration and enrollment certificate is to ensure effective enforcement so that only the duly licensed professionals superintend premises. It further acts as a mechanisms to guarantee access to information. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Committee resolution: Adopted. Pharmacy professionals engaged in professional practice would still be required to display their name and registration certificate.

Paragraph 19
The registration of premises is critical in enforcement. The products must be held by duly qualified professionals. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Justification: The registration of premises is critical in enforcement. The products must be held by duly qualified professionals. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 20
Delete paragraph 20.

Justification: May pose imminent risk to public health and safety by creating a regulatory gap that weakens oversight in non-compliant premises, exposing the public to unsafe practices.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

Paragraph 21
Delete paragraph 21.

Justification: The provision is critical for the Board in outlining the standards and practice of pharmacy. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

General Comments on the Bill by the Pharmacy And Poisons Board(PPB)

PPB highlighted the Practical challenges facing PPB if the Bill is enacted in the current form.
1.Non-compliance with Global Regulatory Standards

- The Board, being the regulator for health products and technologies, must be ranked with other similar regulators by the World health Organization (WHO) and accordingly designated a maturity level based on an established criteria known as the Global Benchmarking Tool (GBT).
- A strong regulator that meets international standards for quality, safety and efficacy is designated under Maturity Level 1 (ML.1).The Board seeks to attain ML.3 which would translate to the ability to independently regulate medical products in accordance with the global standards. The assessment is focused on the following nine essential regulatory areas which must be domiciled within a single regulator;

  - ✓ National Regulatory System
  - ✓ Registration and Marketing Authorization
  - ✓ Vigilance
  - ✓ Market Surveillance and Control
  - ✓ Licensing Premises
  - ✓ Regulatory Inspections
  - ✓ Laboratory Access and Testing
  - ✓ Clinical Trials Oversight
  - ✓ National Lot Release

2. Ongoing WHO GBT Assessment

- Currently, the Board being the regulator for Kenya's health products, is undergoing the WHO assessment seeking to determine how it is effectively undertaking the aforementioned regulatory functions towards ensuring quality, safety and efficacy of health products and technologies within the country.
- The proposed Bill seeks to relieve the PPB of some key regulatory functions with the resultant effect that it will not have the capacity to effectively cover all regulatory areas as required by WHO and global standards.
- The Board has aligned its mandate with these global standards, ensuring Kenya's recognition as a competent regulator currently operating at Maturity Level 2. Fragmentation of these roles and transferring oversight to a new Authority, risks establishing an institution with limited technical expertise, institutional memory, or capacity to meet GBT requirements.

- It is thus critical to ensure that the nine regulatory areas remain domiciled with the regulator (the Board) in compliance with global best practices. The ranking of the Board to a ML.3 will guarantee investor confidence and improve local manufacturing as the quality, safety and efficacy of health products can be guaranteed.

Committee resolution: The Committee noted the general comments by PPB.

47. THE OFFICE OF THE ATTORNEY GENERAL AND DEPARTMENT OF JUSTICE

The Office of the Attorney General and Department of Justice submitted as follows;

The Bill was prepared by the Ministry of Health and submitted to the Office of the Attorney General and Department of Justice for formal drafting as per the established procedure for processing Government Bills. The Bill was drafted in consultation with the Ministry. Therefore, the Bill is in order for consideration by the National Assembly.

Committee resolution: The Committee noted the general comments by the Office of the Attorney General and Department of Justice

48. THE KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD (KMLTTB)

(a) In relation to clauses 40(a) & (b), delete the proposed amendment to section 5 of Cap. 253A in its entirety. Deletion of "business, practice and employment" from subsection (1) and deletion of paragraph (d) in subsection (2), reducing the Board's mandate to training only. The original Cap. 253A under s.5(1) vests "general supervision and control over the training, business, practice and employment of medical laboratory technicians and technologists and over medical laboratories" and s.5(2)(d) includes enforcement of standards and disciplinary control.

Justification: The amendment severs the Board's statutory object of exercising comprehensive supervision over laboratory medicine, directly contradicting the legislative purpose of Cap. 253A. By confining the Board to training alone, the Bill transfers enforcement, practice regulation and laboratory oversight to the new generalist Authority (clauses 27(b), 56–71). This creates immediate duplication and conflict with section 60(1) of the Health Act, 2017, which expressly assigns inspection, monitoring and evaluation of health services and professionals to the respective regulatory body (KMLTTB). Constitutionally, the change violates Article 232(1)(d) (efficient, professional public service) by replacing specialised expertise with generic standards under clause 59, and Article 47 by imposing unfair administrative upheaval without justification. Risks include dilution of laboratory-specific protocols (e.g., equipment validation, reagent quality control, biosafety levels), leading to diagnostic inaccuracies, delayed disease detection, and compromised patient outcomes across HIV, TB, malaria and cancer screening.

The legislative process compounds the problem: Cap. 253A is primary legislation enacted by Parliament; substantive amendments require a dedicated Bill with full First, Second and Third Readings, committee scrutiny and public participation under Articles 10 and 118. Burying them in the Second Schedule of an unrelated Bill

bypasses this process and denies stakeholders meaningful input, contrary to the fundamental duty of Parliamentary Counsel to translate policy into clear, precise, unambiguous law that foresees all eventualities and avoids litigation or policy failure.

The Board's specialised mandate is indispensable to the health sector: it protects the health of every Kenyan through effective regulation of laboratory medicine (Vision), exercises general control and supervision over training, business, employment and practice while advising Government on all related matters (Mission), and performs core functions including licensing, validation of in-vitro diagnostics/equipment/reagents, inspection of facilities and training institutions, CPD enforcement and compliance monitoring. Laboratory services underpin every clinical decision; fragmenting this framework undermines diagnostic accuracy, disease surveillance and universal health coverage.

The Bill goes against the spirit, object and purpose of the MLTT Act by attempting to separate the profession, the professional and the service; an impossibility in medical laboratory practice where one cannot separate professional practice from professional service and quality of service. The gains KMLTTB has made over the last 26 years in building a robust, specialised regulatory framework that protects public health would be erased.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

(b) In relation to clause 39 and clause 43, delete the proposed amendment to section 2 of Cap. 253A and the repeal of section 21 in their entirety.

Justification: Repeal of section 21 dismantles the integrated framework of registration, mandatory continuing professional development (CPD) and annual practising certificates that has safeguarded professional competence in laboratory sciences. Without transitional safeguards in clause 99, over 8,000 licensed professionals face immediate loss of legal authority to practise, triggering exposure to criminal sanctions under Cap. 253A s.19 for "unregistered practice" and violating the doctrine of legitimate expectation. The new Authority's generic licensing (clauses 48–51) cannot replicate laboratory-specific requirements such as CPD in diagnostic techniques, quality assurance or biosafety, creating a high risk of scope creep, unqualified personnel performing complex tests (e.g., PCR, immunoassays, blood banking) and resultant misdiagnosis or treatment errors with potentially fatal consequences. This directly breaches Article 47 (right to fair administrative action and written reasons) and Article 43(1)(a) by endangering the foundational diagnostic pillar of healthcare.

Section 60(1) of the Health Act, 2017 reserves these functions to the respective regulatory body; the duplication is redundant and inefficient. The legislative shortcut via Schedule bypasses the proper parliamentary process required for amending primary legislation such as Cap. 253A (full readings, committee stage, targeted public participation under Articles 10 and 118), risking ambiguity and unforeseen consequences as highlighted in established principles of legislative drafting: hasty or buried amendments lead to litigation, policy failure and inability to foresee practical pitfalls. The Board's framework is vital to the health sector: it enforces CPD, maintains ethical standards and competence, and protects public trust in laboratory results that

drive clinical decisions and national health programmes. Erosion would collapse training pipelines, disrupt private-sector capacity and threaten public health security.

Committee resolution: Adopted. Medical laboratory technicians and technicians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms. Medical laboratory practitioners will still engage in their professional practice.

(c) Delete the proposed complete repeal of section 20 of Cap. 253A in its entirety under clause 42.

Justification: Repeal of section 20 removes foundational provisions supporting registration and practice structures, compounding the vacuum created by other amendments. This leaves no statutory anchor for core licensing pathways, risking immediate invalidation of existing authorisations and operational paralysis in both public and private laboratories. The absence of any transitional mechanism (clause 99) exposes the entire sector to legal uncertainty, contrary to Article 47 and the duty to avoid abrupt disruption of essential services. Section 60(1) of the Health Act, 2017 assigns these functions to the respective regulatory body; the repeal creates conflict and duplication. The Schedule mechanism bypasses proper amendment of Cap. 253A, denying targeted debate. The Board's regulation is indispensable to the health sector: it ensures seamless continuity of accurate, ethical laboratory services that underpin every aspect of healthcare delivery and patient safety.

Committee resolution: Adopted with amendment. Medical laboratory practitioners will still engage in their professional practice.

(d) Delete the proposed amendment to the heading of Part IV and the repeal of section 25 of Cap. 253A in their entirety.

Justification: Repeal of section 25 eliminates the statutory basis for private laboratory operations, which supplement public services and extend diagnostic access nationwide. Private facilities will lose authority to function, leading to closure or forced migration to the Authority's generic regime (clauses 56–64), which lacks tailored standards for laboratory infrastructure, equipment calibration or private-sector quality assurance.

Denial of private practice for medical laboratory professionals is discriminatory and an affront to small and medium businesses run by medical laboratory professionals. This would destroy the entire private laboratories infrastructure that has greatly contributed to medical laboratory profession.

Risks include sudden service gaps in rural and urban private labs, increased patient travel burdens, delayed diagnostics and higher public-sector overload, all contrary to Article 43(1)(a) and the progressive realisation duty. Section 60(1) of the Health Act, 2017 explicitly preserves the Board's oversight of professionals and facilities; the repeal creates conflict and duplication. The legislative shortcut via Schedule bypasses proper amendment of Cap. 253A, denying targeted debate on private-practice implications under Articles 10 and 118. The Board's regulation of private practice is indispensable to the health sector: it ensures ethical, high-quality diagnostics outside

government facilities, supports UHC expansion and prevents monopolistic reliance on public labs that cannot meet growing demand.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals

(e) In clause 44, delete the proposed amendment to section 22 of Cap. 253A in its entirety.

Justification: Deletion removes oversight of private-sector operations and place of business requirements, undermining the Board's ability to regulate the full spectrum of laboratory practice. This creates gaps in enforcement, risks unregulated private facilities and conflicts with the Board's core supervisory role under Cap. 253A. The change violates Article 232(1)(d) and duplicates the Authority's generic licensing without specialised safeguards. The Schedule process circumvents proper parliamentary scrutiny of Cap. 253A amendments. The Board's regulation is vital to the health sector: it maintains comprehensive control over practice to ensure ethical, high-quality diagnostics that protect public health.
Medical laboratory facilities standards are well understood by medical laboratory professionals and inspection by non-professionals will be an occupational nightmare for professionals. The attempt to separate the profession, the professional and the service. One cannot separate professional practice from professional service and quality of service.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals

(f) Delete the proposed amendment transferring disciplinary jurisdiction in Cap. 253A in its entirety from the Board to the new Tribunal.

Justification: Transfer strips the Board of laboratory-specific disciplinary powers (e.g., evaluating diagnostic errors, biosafety breaches), handing them to a generalist Tribunal lacking technical expertise. Risks include inconsistent sanctions, delayed justice and unchecked malpractice leading to patient harm or outbreaks. This violates Article 47 (procedural fairness) and Article 232(1)(d). Section 60(1) of the Health Act, 2017 assigns enforcement to the respective body; the substitution invites parallel proceedings. Amending Cap. 253A via Schedule circumvents dedicated legislative process. The Board's specialised disciplinary mandate is critical to the health sector: it upholds integrity in laboratory results that drive clinical decisions, prevents quackery and maintains public confidence.

The regulation of medical laboratory reagent and equipment will render medical laboratory professionals as spectators who will not be responsible for quality of test results; this means there would be no professional obligation on quality of medical laboratory analyses and investigations.

Committee resolution: Adopted. Medical laboratory technicians and technicians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(g) In clause 47, delete the proposed amendment to section 40 of Cap. 253A in its entirety.

Justification: Loss of regulation-making power prevents the Board from issuing or updating laboratory-specific rules on equipment validation, reagent standards, CPD requirements or inspection protocols. The Authority's generic standards (clause 59) will be ill-suited to clinical diagnostics, risking inconsistent application, equipment failures and biosafety lapses that could cause lab-acquired infections or inaccurate testing. This breaches Article 232(1)(d) and contradicts section 60(1) of the Health Act, 2017. The legislative process for Cap. 253A amendments demands full parliamentary scrutiny; a Schedule insertion denies this. The Board's regulatory authority is vital to the health sector: it enables precise, evidence-based standards that protect diagnostic accuracy and support national health programmes reliant on reliable laboratory data.

The regulation of medical laboratory reagent and equipment will render medical laboratory professionals as spectators who will not be responsible for quality of test results; this means there would be no professional obligation on quality of medical laboratory analyses and investigations.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals

(h) Delete the provisions of clauses 26–27 and Part IV (ss.42–71) and clause 100 insofar as they override or apply to medical laboratories and professionals regulated under Cap. 253A.

Justification: Centralisation overrides Cap. 253A ss.5, 18 and 40, imposing a one-size-fits-all regime cannot accommodate laboratory-specific needs (validation lists, CPD-linked licensing, specialised inspections). Risks include overlapping inspections causing operational delays, conflicting directives, loss of searchable professional and facility registers, and dilution of standards leading to misdiagnosis or compromised biosafety. This violates Article 232(1)(c) (efficient resource use) and section 60(1) of the Health Act, 2017. The Schedule mechanism bypasses proper amendment of Cap. 253A. The Board's dedicated oversight is indispensable to the health sector: it safeguards the integrity of laboratory medicine, the backbone of clinical diagnosis, treatment monitoring and public health surveillance.

Committee resolution: Not adopted. The clauses are in order as drafted. The Authority will accredit for purposes of quality healthcare.

(i) Delete clause 99 and clause 100 insofar as they omit transitional protections for matters under Cap. 253A.

Justification: Without transition, existing licences, training approvals and disciplinary cases lapse immediately, creating legal uncertainty for professionals, institutions and facilities. Risks include abrupt service interruptions, loss of continuity in student indexing and CPD, wasted investment in Board systems and registers, and exposure of patients to unregulated diagnostics. This breaches Article 47 and legitimate expectation while conflicting with section 60(1) of the Health Act, 2017. Amending Cap. 253A via Schedule without transition safeguards denies due process under Articles 10 and 118. The Board's framework is vital to the health sector: it

ensures seamless continuity of accurate, ethical laboratory services that underpin every aspect of healthcare delivery and patient safety.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals

49. NURSING COUNCIL OF KENYA (NCK)

(a) Amend clause 27(j) to "inspect and accredit health facilities in collaboration with the relevant regulatory body for purposes of internship and training.

Justification: Different programmes across the various health training cadres require distinct infrastructure and facility capacities to effectively support learning. Consequently, requests to utilize specific health facilities for training are submitted to the relevant regulatory bodies. These regulatory bodies assess and approve facilities to ensure that the requisite infrastructure, equipment, and case mix are available to support the training needs of particular programmes.

In this regard, regulators such as the Nursing Council maintain a comprehensive database of health facilities utilized by training institutions for nursing and midwifery education. This database not only supports quality assurance but also helps prevent oversaturation of students within particular facilities, which could otherwise dilute clinical exposure and compromise both training quality and patient care. Restricting regulatory bodies from continuing to perform this role may lead to fragmentation and uncertainty in the approval and implementation of nursing and midwifery programmes, ultimately undermining coordinated oversight and quality standards in health training.

Committee resolution: Adopted with amendment. Health professional regulatory bodies to retain the function of inspecting and accrediting health facilities for purposes of internship and training.

(b) Proposed new subclause to read:

Amendment of Section 17 of Cap 257

The Nurses and Midwives Act is amended by inserting the following new section 17A after section 17 –

Practising Certificate

A person shall not practise a nurse, midwife, Healthcare Assistant, Theatre Technician or Theatre Technologist or enjoy a public position by virtue of being a nurse, midwife, Healthcare Assistant, Theatre Technician or Theatre Technologist unless such a person has—

(a)been registered under this Act;
(b) complied with the prescribed requirements for continuing education and supervision; and
c) been issued with a valid practicing certificate by the Council in accordance with

this Act.

Justification: The continued existence of numerous unregulated healthcare cadres operating under the supervision of regulated professionals presents a significant gap in the realization of the objectives of the Quality Healthcare and Patient Safety Bill, 2025. These cadres often lack clearly defined scopes of practice, standardized training frameworks, and accredited curricula, which raises concerns regarding the consistency, safety, and quality of care delivered to patients particularly upon transition from training to independent or semi-autonomous practice.

This regulatory vacuum undermines the intent of the Bill, which is to promote accountability, standardization, and patient safety across the health sector. Without formal oversight mechanisms, it becomes difficult to enforce professional standards, monitor competence, or address malpractice among such cadres. To address this challenge, it is imperative that all unregulated healthcare cadres be formally integrated under their respective parent regulatory bodies, particularly where supervisory relationships already exist in practice. Such incorporation would ensure that these cadres are subject to established regulatory frameworks, including licensing, defined scopes of practice, competency assessments, and continuous professional development requirements.

Bringing all healthcare providers within a structured regulatory ambit will not only enhance accountability and harmonization of standards but also significantly strengthen the implementation of the Bill by ensuring that every individual involved in patient care is adequately trained, supervised, and regulated in accordance with national quality and safety standards.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals.

50. **CLINICAL OFFICERS COUNCIL**

(a) Paragraph 1

(i) Retain the definition of "Health care provider" as is in the Health Act.

Justification: A person providing health care services must be trained, licenced and regulated by the relevant regulatory body. The proposed definition is ambiguous and there is need for specificity and clarity.

Committee resolution: Adopted. The definition of the term "healthcare provider" is more comprehensive as it includes a healthcare professional providing healthcare services.

(ii) delete and replace the definition of a health facility as follows:

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

telemedicine services, medical aesthetic procedures and community health services.

Justification: The definition of a "person" as a facility is confusing and does not provide the clarity of "natural person" or the "legal person".

Committee resolution: Not adopted. The current definition is sufficient in the circumstances.

(b) Clause 19

Clause 19(1)(c) of the proposed Bill to be amended to read as "Adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as developed by the respective regulatory body and approved by the Cabinet Secretary".

Justification: The establishment of the Scopes of Practice to be retained at the respective regulatory bodies i.e COC, NCK, KMPDC etc. Notably, the Director-General of Health already serves as a board member on most of these Councils, ensuring government representation and alignment with national policy.Each carder is governed by an Act of parliament that establishes its regulatory council that is mandated to develop, update and reinforce the various scopes of practice. The Scope of Practice for Clinical Officers like any other carder sets forth the legislative and regulatory framework for guiding all Clinical Officers licensed to practice in Kenya to perform their duties safely while ensuring that all patients are protected from harm and that they receive the best possible healthcare to the highest attainable standards. It outlines the key areas of competencies (knowledge, skills and attitude), professional roles and responsibilities for Clinical Officers in practice both at general and specialized levels.

Committee resolution: Adopted with amendment. The Director-General for Health ought to perform the role of developing scope of practice as the Director-General is the technical advisor on matters touching on the health sector.

Clause 19 (2) be amended to read as "A Kshs. 500,000 thousand fine or 3-year imprisonment".

Justification: A fine/penalty should be procedurally proportionate fair, just and affordable The fine is fixed and is not taking the consideration of the facility level and professional, its also way above as provided in the Penal Code.

Committee resolution: Adopted with amendment to reduce the fine and remove the element of imprisonment. The proposed penalty was too punitive and yet most of the issues may be systemic in nature.

(c) Second Schedule- Proposed a two tier quality assurance system as detailed below:

Two Tier Verification framework

- i. Tier one - registration and licensure by the respective regulatory body
- ii. Tier two- verification and accreditation by a different body (suggested to be KHPOA), before empanelment. and; Restructuring KHPOA to expand its mandate into accreditation and quality of care.

Justification: The Health Act No. 21 of 2017 needs to be amended to restructure and expand the functions of KHPOA, which will give it an accreditation mandate as well as monitoring and ensuring that the highest standards of health services are maintained through 'quality of care inspections and accreditation' as provided under article 43 of the Constitution. On duplication of roles, the Judgement of September 2022 on Health Act interpreted KHPOA to be the ultimate body responsible for Quality of Healthcare in Kenya. There is therefore no need to bring in another SAGA when KHPOA can be improved to serve its purpose. Lack of operationalization of KHPOA after 7 years has been a deliberate act to create a perception that it can't serve its purpose. 2. Kakamega Cabinet Resolution Feb 2025 which directed for merger, dissolution or declassification to reduce financial demand. Introduction of another SAGA that serves the role of KHPOA goes against the principles of that resolution.

(d) Paragraph 35, 36 and 37 of the Second Schedule

Retain sections 20, 23 and 23A of the Clinical Officers Act, No. 20 of 2017 proposed for amendment .

Justification: Regulation of Health facilities by the relevant regulatory body which also regulates training and practice of the relevant professionals is better placed to monitor quality service delivery since they understand their scope. In the Two Tier Verification framework for quality purposes i.e i. Tier one - registration and licensure by the respective regulatory body and ii. Tier two- verification and accreditation by a different body (suggested to be KHPOA), before empanelment, therefore the functions of the Council should be retained as this framework caters for quality.

Committee resolution: Not adopted. The amendments are necessary for purposes of separating the regulation of health facilities from that of healthcare professionals

(e) Paragraph 38, 39, 40, 41, 42 and 43.

Retain the sections proposed for deletion under these paragraphs.

Justification: No justification provided to support their deletion or amendment.

Committee resolution: Adopted. The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

(f) Clause 29

Improve representation of County Governments to include;

1. One member nominated by forum for County Secretaries
2. One member nominated by the forum for CECM Health
3. One member nominated by the forum for Chief Officers.

Justification: The Board composition has only one representative of County Governments yet County Governments manage > 90% of facilities.

Committee resolution: Not adopted. The current composition has sufficient county representation.

General Comments on the Bill

(a) The WHO defines quality health services as those that are effective, safe, people-centered, timely, equitable, integrated, and efficient. These characteristics are often assessed using quality indicators, which are standardized, evidence-based measures that help monitor and track healthcare performance and outcomes. These include:

- Effectiveness: Providing services based on scientific knowledge to all who could benefit e.g. maternal health indicators (rates of severe maternal morbidity and mortality). Lack of diagnostics, equipment and other essential utilities serve as hindrances to this.
- Safety: Avoiding harm to patients from the care care provided e.g hospital-acquired infections, adverse drug events among others. Lack of adequate Personal Protective Gear continues to impact safety negatively.
- People-centeredness: Providing care that respects individual patient preferences, needs, and values e.g patient satisfaction with care, Involvement of patients in treatment decisions and Availability of patient education and support. Staff shortages continue to lower Patient Satisfaction due to long waiting times and burnout among clinicians.
- Timeliness: Reducing waits and delays for both patients and providers e.g. Time to treatment initiation and Availability of services outside of regular business hours among others. Negatively affected by staff shortages, poor digital infrastructure among others.
- Equity:Providing care that does not vary in quality due to factors like location or socioeconomic status e.g disparities in access to care based on location and Disparities in outcomes based on socioeconomic status among others. Disparities in access to care still exist especially in rural and hardship areas where specialists are few and often overwhelmed.
- Efficiency: Avoiding waste of resources e.g appropriate use of resources.
- Integration: Providing coordinated and continuous care. e.g. Communication and coordination between different healthcare providers, Continuity of care between different settings (e.g., hospital to home) and Availability of electronic health records and information sharing. Mostly limited/affected by poor digital infrastructure.

(b) >80% of contents in the Quality of Healthcare and Patient Safety Bill 2025 are already provided for in other legislations and policies within the ministry including; Health Act 2017, National Policy on Patient Safety, Health Worker Safety and Quality of Care, Public Health Act, Clinical Officers Act, Medical Practitioners and Dentists Act, Nurses Act, Kenya Quality Model of Health (KQMH) policy, Medical Laboratory Technicians and Technologists Act, Nutrition and Dieticians Act, PHOTC Act, Pharmacy and Poisons Act, among others.

(c) The Judgement by Judge Wesley Korir of September 2022 directed for amendment of Health Act 2017, which provides a shorter and cost-effective route for its improvement, if need be, without reproducing and duplicating laws that provide for health. Management and continuous monitoring of Quality of Healthcare is already provided for in several legislations and policies as indicated above, meaning this bill will not change anything as far as quality of healthcare is concerned.

(d) The Council identified the following issues with the Bill:

- Duplication and Confusion. -The Bill will create confusion and duplication of roles by replicating other Acts e.g. rights and duties under Health Act and Public Health Act provisions among many others.
- Weak Quality Assurance Framework. -The biggest problem that has affected quality of care with regard to health facilities has been the wrong designation of health facilities due to weak quality assurance mechanisms which do not provide for verification. -This bill still retains this problem where one entity registers, licenses and accredits facilities which has led to corruption and the consequent poor quality of health. This is because facilities were allocated erroneous levels that neither matched their resources nor capacity due to lack of an independent verification system. -A strong and progressive Quality Assurance Mechanism should have a two tier accreditation system, where the relevant regulatory body registers and licenses and then an independent body verifies and accredits.
- Interference with development of Scopes of Practice. Transfer of Mandate on development of Scopes of Practice from regulatory bodies Director General is retrogressive and will negatively affect quality of health. to Councils and Boards are better placed to continue with this function since they have a diversity of members representing various fields including trainers, regulators, legal practitioners and practitioners in the relevant field, which provides a better and informed forum for development of progressive Scopes of Practice.
- Duplication of Roles-The Judgement of September 2022 on Health Act interpreted KHPOA to be the ultimate body responsible for Quality of Healthcare in Kenya. There is therefore no need to bring in another SAGA when KHPOA can be improved to serve its purpose. Lack of operationalization of KHPOA after 7 years has been a deliberate act to create a perception that it can't serve its purpose.
- Kakamega Cabinet Resolution of Feb 2025.The Kakamega cabinet resolution 2025 directed for merger, dissolution or declassification in view of the tight fiscal space within the reality of rising debt burden. Introduction of another SAGA that serves the role of KHPOA goes against the principles of that resolution and is totally unnecessary.

(e) The Council submitted that the real issues that threaten quality of healthcare currently include;

- Financing - inadequate budgetary allocation to health
- Staff shortage - there is no clear framework on resolving HRH staff shortages
- Service disruption from perennial strikes
- Poor digital infrastructure.
- Demoralization and demotivation of health workers.
- Poor coordination between National and County Governments.
- Political interference.
- Over legislation without the required implementation.

(f) The Council recommended the following:

- Withdrawal of the Quality of Healthcare and Patient Safety Bill 2025 and instead amends Health Act 2017.
- Alignment of budgetary allocation to health with Abuja Declaration of 2001 that provided for allocation of 15% of the total budget.

- Development of a framework for annual employment of 12,000 health workers in line with Kenya's Human Resources for Health Commitments at the 2013 Third Global WHO HRH Forum in Brazil.
- Fast tracking of amendments to the Health Act and designation of KHPOA as the Quality of Healthcare Authority in line with Justice Wesley Korir's Judgement of September 2022.
- Full Implementation of Health Act 2017 by fully operationalizing Kenya Health Professionals and Oversight Authority and Kenya Health Human Resources Advisory Council.
- Negotiation, Completion and full implementation of Collective Bargaining Agreements as well as signing Recognition Agreements to reduce service disruption through strikes.

CHAPTER FOUR

4.0 COMMITTEE OBSERVATIONS

51. The Committee observes that:

1. The Quality Healthcare and Patient Safety Bill, 2025 establishes a unified legal and institutional framework to guarantee safe, effective, timely and people-centred health services in Kenya. Its core objects are to guarantee patient rights and safety, set and enforce national standards for health facilities, and create mechanisms for continuous quality improvement and oversight across the health system.

2. The Bill is a significant step towards ensuring that the country's investments in Universal Health Coverage (UHC) translate into safe, quality effective and people-centred care through institutionalization of standards, accreditation and enforcement of quality healthcare standards through a dedicated national regulator.

3. The Bill seeks to establish the Quality Health Care and Patient Safety Authority as the sole national regulator responsible for the registration, licensing and accreditation of all health facilities.

4. The Bill seeks to separates facility-level regulation from professional licensure and regulation which will be undertaken by the respective health regulatory bodies and hence the consequential amendments in the Second Schedule.

5. The Bill seeks to establish a Health Care Tribunal to hear appeals and adjudicate all disputes relating to the provision of healthcare services.

CHAPTER FIVE

5.0 COMMITTEE RECOMMENDATIONS

52. The Committee **recommends that the House passes** the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025) with amendments as set out in Chapter Six of this report.

CHAPTER SIX

6.0 SCHEDULE OF AMENDMENTS

53. Upon considering the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025) and submissions from stakeholders, the Committee proposes the following amendments:

CLAUSE 18
THAT, Clause 18 of the Bill be amended in—

(a) subclause (1) by inserting the words "on the recommendation of the Director General" immediately after the term "Cabinet Secretary" appearing in paragraph (c).

Justification: The Director-General for Health ought to perform the role of developing scope of practice as the Director-General is the technical advisor on matters touching on the health sector.

(b) subclause (2) by deleting the words "fifty million shillings or to imprisonment for a term not exceeding ten years, or to both" and substituting therefor the words "ten million shillings".

Justification: The proposed penalty was too punitive and yet most of the issues may be systemic in nature.

CLAUSE 23
THAT, Clause 23 of the Bill be amended in paragraph (b) by inserting the words "for their employees" immediately after the word "training".

Justification: To specify that the training is for the employees of the owner of a health facility.

CLAUSE 27
THAT, Clause 27 of the Bill be amended by deleting paragraph (j).

Justification: Health professional regulatory bodies to retain the function of inspecting and accrediting health facilities for purposes of internship and training.

CLAUSE 29
THAT, Clause 29 of the Bill be amended—

(a) in subclause (1) by—

(i) inserting the words "in the health sector" immediately after the word "improvement" appearing in paragraph (f);

Justification: To ensure that expertise is relevant to the improvement of the quality of healthcare services.

(ii) deleting the words "to represent" appearing in paragraph (g) and substituting therefor the words "nominated by";

Justification: To enable healthcare providers who have established and recognized organized entities to nominate suitable persons to represent their interests in the proposed Authority.

(iii) deleting the word "public" appearing in paragraph (h) and substituting therefor the words "consumer rights bodies in the health sector"; and

Justification: To ensure that the person appointed is able to articulate issues relating to the rights of patients and clients as consumers of healthcare services.

(iv) inserting the following new paragraph immediately after paragraph (h)—

"(ha) a representative of statutory regulatory bodies appointed by the Cabinet Secretary".

Justification: This will ensure that the interests of statutory regulatory bodies are well take into account by the proposed Authority.

CLAUSE 30

THAT, Clause 30 of the Bill be amended in—

(a) subclause (1) by—

(i) deleting the words "a healthcare related field" appearing in paragraph (b) and substituting therefor the words "healthcare sciences".

Justification: The Chairperson ought to have knowledge and expertise in healthcare sciences to offer the necessary strategic leadership.

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

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

Justification: Ten years professional practice, knowledge and experience is ideal for the position of Chairperson.

(iii) deleting the word "ten" appearing in paragraph (d) and substituting therefor the word "five".

Justification: Five years of senior management level is ideal for the position of Chairperson.

(b) in subclause (2) by inserting the words "healthcare sciences" immediately after the words "social sciences" appearing in paragraph (c).

Justification: The Board of the Quality Healthcare Authority needs to have knowledge and expertise in healthcare sciences to offer the necessary strategic direction.

CLAUSE 35

THAT, Clause 35 of the Bill be amended in clause (2) by deleting the words "a healthcare related field" appearing in paragraph (b) and substituting therefor the words "healthcare sciences".

Justification: The Chief Executive Officer ought to have knowledge and expertise in healthcare sciences to ensure effective management of the Authority.

CLAUSE 37

THAT, Clause 37 of the Bill be amended by deleting subclause (3) and substituting therefor the following new subclause (3)—

"(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 legal advice 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."

Justification: For clarity on the role of the Corporation Secretary in line with Mwongozo Code of Governance for State Corporations.

CLAUSE 57

THAT, Clause 57 of the Bill be amended in subclause (2) by inserting the following new paragraph immediately after paragraph (a)—

"(aa) appoint quality assessors to conduct the accreditation of health facilities".

Justification: To empower the proposed Authority to appoint experts in quality improvement and assessment to undertake the function of accreditation.

CLAUSE 83

THAT, Clause 83 of the Bill be amended —

(a) in subclause (1) by deleting the words "or any other written law";

Justification: The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

(b) by deleting subclause(2);

Justification: The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

(c) by deleting subclause (3);

Justification: The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

(d) in subclause (4) by—

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

"(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"

(ii) inserting the following new paragraph immediately after paragraph (c)—

"(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.";

Justification: The Health Care Tribunal requires a skills mix that includes healthcare professionals for purposes of ensuring fairness and sound judgement in its processes.

(e) in subclause (7) by deleting the term " Cabinet Secretary" and substituting therefor the term "Judicial Service Commission"; and

Justification: Tribunals fall within the ambit of the Judiciary.

(f) in subclause (8) by deleting the term " Cabinet Secretary" and substituting therefor the term "Chief Justice".

Justification: Tribunals fall within the ambit of the Judiciary.

CLAUSE 84

THAT, Clause 84 of the Bill be amended in —

(a) subclause (1) by deleting the words "or any other Act"; and

Justification: The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

(b) subclause (3) by deleting the words "between health facilities, patients, healthcare providers and regulatory bodies" and substituting therefor the words "relating to health facilities and patients".

Justification: The proposed Health Care Tribunal will only have jurisdiction over complaints and disputes in relation to the functions of the Quality Healthcare and Patient Safety Authority in the regulation of health facilities.

CLAUSE 99

THAT, Clause 99 of the Bill be amended by inserting the following new subclause immediately after subclause (3)—

"(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 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.

Justification: The staff currently handling the function of registration, licensing, inspection and
disciplinary matters of health facilities will move to the Authority with their institutional memory and expertise.

SECOND SCHEDULE

THAT, the Second Schedule be amended —

(a) in paragraph (1) by deleting subparagraph (a);

Justification: The definition of the term "healthcare provider" is more comprehensive as it includes a healthcare professional providing healthcare services.

(b) by deleting paragraph (3);

Justification: The Director-General ought to perform the role of developing all guidelines as the Director-General is the technical advisor on matters touching on the health sector.

(c) in paragraph (5) by—

(i) deleting subparagraph (a) and substituting therefor the following new subparagraph (a)—

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

(ii) deleting subparagraph (b) and substituting therefor the following new subparagraph (b)—

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

Justification: To limit the role of the Kenya Health Professionals Oversight Authority to the regulation of healthcare professionals.

(d) by deleting paragraph (9);

Justification: The Kenya Health Professionals Oversight Authority and other regulatory bodies will undertake inspection as regards the regulation of healthcare professionals.

(e) by deleting paragraph (11);

Justification: Some health centres are permitted to provide in-patient observations based on their level of categorization by the regulator.

(f) by deleting paragraph (13);

Justification: Pharmacy professionals aggrieved by the decisions of the Pharmacy and Poisons Board will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(g) in paragraph (15) by –

(i) deleting the expression "word "tribunal"" appearing in subparagraph (a) and substituting therefor the expression "term "High Court""; and

(ii) deleting the expression "word "tribunal"" appearing in subparagraph (b) and substituting therefor the expression "term "High Court"";

Justification: Pharmacy professionals aggrieved by the decisions of the Pharmacy and Poisons Board will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(h) in paragraph (16) by deleting the expression "word "tribunal"" appearing immediately after the words "therefore the" and substituting therefor the expression "term "High Court"";

Justification: Pharmacy professionals aggrieved by the decisions of the Pharmacy and Poisons Board will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(i) in paragraph (17) by deleting the expression "word "tribunal"" appearing immediately after the words "therefore the" and substituting therefor the expression "term "High Court"";

Justification: Pharmacy professionals aggrieved by the decisions of the Pharmacy and Poisons Board will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(j) by deleting paragraph (18);

Justification: Pharmacy professionals engaged in professional practice would still be required to display their name and registration certificate.

(k) by deleting paragraph (22).

Justification: The definitions of the terms "mental health facility" and "mental health services" are in order as they are presently defined in the Mental Health Act, Cap. 248. A person aggrieved by the decisions made under the Mental Health Act, Cap. 248 will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(l) by deleting paragraph (25);

Justification: A person aggrieved by the decisions made under the Mental Health Act, Cap. 248 will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(m)by deleting paragraph (26);

Justification: A person aggrieved by the decisions made under the Mental Health Act, Cap. 248 will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(n) in paragraph (27) by deleting subparagraph (d);

Justification: Medical practitioners and dentists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms in relation to professional practice.

(o) in paragraph (28) by deleting subparagraph (a);

Justification: The Kenya Medical Practitioners and Dentists Council needs to retain the power to inspect and accredit new and existing institutions for medical and dental internship training in Kenya as the same relates to the regulation of the professional practice.

(p) by deleting paragraph (29);

Justification: The Kenya Medical Practitioners and Dentists Council needs to retain the power to inspect and accredit new and existing institutions for medical and dental internship training in Kenya as the same relates to the regulation of the professional practice.

(q) in paragraph (30) by deleting subparagraph (a);

Justification: The Kenya Medical Practitioners and Dentists Council needs to maintain a register of approved internship training centres as the same relates to the regulation of the professional practice.

(r) by deleting paragraph (31);

Justification: Medical practitioners and dentists aggrieved by the decisions made under the Medical Practitioners and Dentists Act, Cap. 253 will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(s) in paragraph (36) by deleting subparagraph (d);

Justification: Medical practitioners and dentists aggrieved by the decisions made under the Medical Practitioners and Dentists Act, Cap. 253 will have the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(t) by deleting paragraph (39);

Justification: Medical laboratory technicians and technicians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(u) in paragraph (42) by deleting—

(i) subparagraph (b)(ii) and (iii); and
(ii) subparagraph (c);

Justification: Medical laboratory practitioners will still engage in their professional practice.

(v) by deleting paragraph (43);

Justification: Medical laboratory practitioners will still engage in their professional practice.

(w) by deleting paragraph (45) and substituting therefor the following new paragraph—

"45.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";
(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";

Justification: Medical laboratory practitioners will still engage in their professional practice.

(x) by deleting paragraph (46);

Justification: Medical laboratory technicians and technicians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(y) in paragraph (48) by deleting subparagraph (b);

Justification: Nutritionists and dieticians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(z) by deleting paragraph (49);

Justification: Nutritionists and dieticians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(aa)by deleting paragraph (51);

Justification: Nutritionists and dieticians will still engage in their professional practice.

(bb) by deleting paragraph (52);

Justification: Nutritionists and dieticians retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(cc) by deleting paragraph (54);

Justification: Counsellors and psychologists the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(dd) by deleting paragraph (56);

Justification: Counsellors and psychologists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ee) by deleting paragraph (57);

Justification: Counsellors and psychologists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ff) in paragraph (59) by deleting the definition of the term "tribunal";

Justification: Physiotherapists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(gg) in paragraph (60) by deleting subparagraph (b) and substituting therefor the following new subparagraph (b)—

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

Justification: Physiotherapists will still engage in their professional practice.

(hh) in paragraph (62) by deleting subparagraph (c) and substituting therefor the following new subparagraph (c)—

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

Justification: Physiotherapists will still engage in their professional practice.

(ii) by deleting paragraph (63);

Justification: Physiotherapists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(jj) in paragraph (64) by deleting subparagraph (b) and substituting therefor the following new subparagraph (b)—

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

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

Justification: Physiotherapists will still engage in their professional practice.

(kk) in paragraph (66) by deleting the definition of the term "tribunal" appearing in subparagraph (c);

Justification: Clinical officers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ll) by deleting paragraph (67);

Justification: Clinical officers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(mm) in paragraph (69)—

(i) in subparagraph (c) by inserting the words "and substituting therefor the word "professional" immediately after the word "private";

(ii) by deleting subparagraph (d) and substituting therefor the following new subparagraph(d)—

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

(iii) by deleting subparagraph (e) and substituting therefor the following new subparagraph (e) —

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

Justification: Clinical officers will still engage in their professional practice.

(nn) in paragraph (71) by deleting subparagraph (b);

Justification: Clinical officers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(oo) by deleting paragraph (72) and substituting therefor the following new paragraph—

"72.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".

Justification: Clinical officers will still engage in their professional practice.

(pp) by deleting paragraph (75);

Justification: Clinical officers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(qq) by deleting paragraph (78);

Justification: Radiographers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(rr) in paragraph (81) by deleting subparagraph (c) and substituting therefor the following new subparagraph—

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

Justification: Radiographers will still engage in their professional practice.

(ss) by deleting paragraph (82);

Justification: Radiographers will still engage in their professional practice. Radiographers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(tt) in paragraph (83) by deleting subparagraph (b) and substituting therefor the following new subparagraph—

"(b) by 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";

Justification: Radiographers will still engage in their professional practice.

(uu) by deleting paragraph (84);

Justification: Public health officers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(vv) by deleting paragraph (85);

Justification: Public health officers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ww) in paragraph (88) by deleting the definition of the term "tribunal";
Justification: Occupational therapists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(xx) in paragraph (91) by deleting subparagraph (e);

Justification: Occupational therapists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(yy) by deleting paragraph (92) and substituting therefor the following new paragraph—

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

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

(b) in 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";

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

Justification: Occupational therapists will still engage in their professional practice.

(zz)by deleting paragraph (94) and substituting therefor the following new paragraph—

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

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

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

(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".

Justification: Occupational therapists will still engage in their professional practice.

(aaa) by deleting paragraph (95);

Justification: Occupational therapists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(bbb) by deleting paragraph (96);

Justification: Occupational therapists retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ccc) in paragraph (99) by deleting subparagraph (b);

Justification: Nurses and midwives retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ddd) by deleting paragraph (102);

Justification: Nurses and midwives retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(eee) in paragraph (105) by deleting subparagraph (e);

Justification: Health records and information managers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(fff) by deleting paragraph (109);

Justification: Health records and information managers retain the right to appeal to the High Court after exhaustion of the internal and administrative mechanisms.

(ggg) by deleting paragraph (110);

Justification: The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

(hhh) by deleting paragraph (111);

Justification: The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

(iii) by deleting paragraph (112); and

Justification: The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

(jjj) by deleting paragraph (113).

Justification: The Dispute Resolution Tribunal provided for in the Social Health Insurance Act, No. 16 of 2023 should not be repealed since health insurance matters are unique and require expertise in its handling.

SIGNED..... **DATE**.....8/4/2026.

HON. DR. JAMES NYIKAL WAMBURA, CBS, M.P.
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

THE NATIONAL ASSEMBLY
PAPERS LAID
DATE: 09 APR 2026 DAY. Thursday
TABLED BY: Chair Health Committee
CLERK-AT THE-TABLE: Kaula-Idiiri

REPORT ADOPTION SCHEDULE

THE NATIONAL ASSEMBLY
13TH PARLIAMENT - FIFTH SESSION – 2026

DIRECTORATE OF DEPARTMENTAL COMMITTEES
DEPARTMENTAL COMMITTEE ON HEALTH

ADOPTION SCHEDULE

Having considered the Report on the Consideration of the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025), we the undersigned adopt the report.

Date: Tuesday, 7th of April 2026

NO.	NAME	SIGNATURE
1.	Hon. **(Dr.)** Nyikal James Wambura, **CBS,** MP- **Chairman**	
2.	Hon. Ntwiga Patrick Munene, MP- **Vice-Chairman**	
3.	Hon. Sunkuli Julius Lekakeny Ole, **EGH**, **EBS**, MP	
4.	Hon. **(Dr.)** Pukose Robert, **CBS**, MP	
5.	Hon. **(Bishiop)** Mukhwana Titus Khamala, MP	
6.	Hon. Owino Martin Peters, MP	
7.	Hon. **(Prof.)** Jaldesa Guyo Waqo, MP	
8.	Hon. Maingi Mary, MP	
9.	Hon. Muge Cynthia Jepkosgei, MP	
10.	Hon. Lenguris Pauline, MP	
11.	Hon. Oron Joshua Odongo, MP	
12.	Hon. Mathenge Duncan Maina, MP	
13.	Hon. Wanyonyi Martin Pepela, MP	
14.	Hon. Kipngok Reuben Kiborek, MP	
15.	Hon. Kibagendi Antoney, MP	

MINUTES OF COMMITTEE SITTINGS

MINUTES OF THE 23RD SITTING OF THE DEPARTMENTAL COMMITTEE ON HEALTH HELD IN COMMITTEE ROOM 21, 5TH FLOOR, BUNGE TOWER ON TUESDAY, 7TH APRIL, 2026, AT 11.30 AM

PRESENT

1.	The. Hon. Dr. Nyikal James Wambura,CBS, MP	**-Chairperson**
2.	The Hon. Dr. Pukose Robert,CBS,MP	**-Member**
3.	The Hon. Prof. Jaldesa Guyo Waqo, MP	-Member
4.	The Hon. Oron Joshua Odongo, MP	-Member
5.	The Hon. Mary Maingi, MP	-Member
6.	The Hon. Cynthia Muge, MP	-Member
7.	The Hon. Owino Martin Peters, MP	-Member
8.	The Hon. Kipngor Reuben Kiborek, MP	-Member
9.	The Hon. Lenguris Pauline, MP	-Member
10.	The Hon. Titus Khamala, MP	-Member

ABSENT WITH APOLOGY

1.	The Hon. Ntwiga Patrick Munene, MP	-Vice Chairperson
2.	The Hon Wanyonyi Martin Pepela, MP	-Member
3.	The Hon. Mathenge Duncan Maina, MP	- Member
4.	The Hon. Sunkuli Julius Lekakeny Ole, EGH, EBS, MP	-Member
5.	The Hon Wanyonyi Martin Pepela, MP	-Member

COMMITTEE SECRETARIAT

1.	Mr. Adan Gindicha II-HOD	-Principal Clerk Assistant
2.	Ms. Gladys Kiprotich	-Clerk Assistant III
3.	Mr. Ellam Omuhinda	-Clerk Assistant III
4.	Ms. Faith Chepkemoi	-Legal Counsel II
5.	Ms. Mercylyn Kerubo	- Audio Officer
6.	Mr.Daniel Psirmoi	-Media Relations Officer

IN AGENDA

1. Prayers
2. Preliminaries
3. Adoption of the Agenda
4. Confirmation of previous minutes
5. Matters Arising
6. **Meeting to adopt the report on the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025) sponsored by the Hon. Leader**

7. Pending Business (enclosed)
8. Any Other Business; and
9. Adjournment.

MIN. NO. NA/DC-H/2026/112: PRELIMINARIES/INTRODUCTION

The Chairperson called the meeting to order at thirty minutes past eleven o'clock, followed by the Prayer and self-introductions.

MIN. NO. NA/DC-H/2026/113: ADOPTION OF AGENDA

The agenda of the meeting was adopted, having been proposed by the Hon. Owino Martin Peters, MP and seconded by the Hon. Dr. Pukose Robert, CBS, MP.

MIN. NO. NA/DC-H/2026/114: MEETING TO ADOPT THE REPORT ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL (NATIONAL ASSEMBLY BILL NO. 41 OF 2025) SPONSORED BY THE HON. LEADER

Key Concerns Raised by Members

Members raised the following substantive concerns regarding the Bill:

1) **Impact on Existing Regulatory Authorities;**

Members expressed serious concern that the enactment of the Bill would result in significant consequential amendments to the mandates of existing statutory regulatory authorities including the Kenya Medical Practitioners and Dentists Council (KMPDC), the Pharmacy and Poisons Board, the Nursing Council of Kenya, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), and the Clinical Officers Council to the extent that they would be stripped of their mandate to regulate health facilities. This would effectively remove a primary source of revenue for these bodies, potentially rendering them financially unviable unless directly funded from the Exchequer.

It was further noted that information had been received that the Office of the Attorney General was already undertaking work towards the possible merger of all statutory regulatory authorities into a single body. Members felt this development had significant implications for the Bill and warranted careful consideration.

2) **Duplication and Efficacy of the Bill's Objects**

Members questioned whether the Bill's stated objects introduced any substantive new framework, noting that the objectives including guaranteeing patient rights and safety, setting standards for health care services, and improving quality of health outcomes were largely covered by existing policy frameworks, Acts, and regulatory mandates already in operation.

3) **Definition of 'Quality Healthcare'**

Concern was raised that the Bill did not adequately define 'quality healthcare.' Members, emphasized the need for a clear, measurable definition that would distinguish the Bill's intended outcomes from existing policy commitments, particularly in respect of the parity between public and private sector service delivery.

4) **Regulatory Fragmentation vs. Consolidation**

Members acknowledged that the current regulatory landscape was fragmented, with multiple bodies KMPDC, the Pharmacy and Poisons Board, the Nursing Council Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB)and others each independently inspecting and licensing the same health facilities, resulting in an administrative and financial burden on facility operators. To this extent, the creation of a single facility-level regulatory authority was seen as a potentially positive development.

However, concern remained as to how the separation of facility regulation from professional regulation would function in practice, and whether the two functions could be meaningfully disaggregated.

5) **Composition of the Proposed Authority's Board**

Members reviewed the proposed composition of the Board of the Quality Healthcare Authority as set out in Clause 29 of the Bill.

The Committee recalled an amendment proposed during the Mombasa retreat to include a representative of statutory regulatory bodies drawn from KMPDC, KMLTTB, and the Nursing Council) appointed by the Cabinet Secretary on a rotational basis, consistent with the approach adopted under the Kenya Health Professionals Oversight Authority (KHPOA).

The committee emphasized that a representative of statutory regulatory bodies appointed by the Cabinet Secretary will ensure that the interests and perspectives of statutory regulatory bodies are adequately represented and taken into account within the operations and decision-making processes of the proposed Authority.

Committee's Resolutions and Way Forward

After deliberation, the Committee resolved as follows:

1) The Committee would agree the Bill to proceed to be tabled in the House with the amendments already proposed. Members noted that further amendments could be introduced at the Committee of the Whole House stage

2) The Chairperson undertook to engage the Leader of the Majority Party to request additional time to enable the Committee to conduct a benchmarking study of comparative jurisdictions specifically Malaysia and Singapore to inform the Committee's final position on the Bill's implementation framework.

3) As an alternative to international travel, a desktop research study on best practices in quality healthcare regulation in comparable jurisdictions would be commissioned for Members' reference.

4) The Clerk was directed to facilitate the preparation of any further draft amendments for Members' consideration in advance of the Committee of the Whole House stage.

The Committee therefore adopted the report on the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025) sponsored by the Hon. Leader of the Majority Party, having been proposed by Hon. Owino Martin Peters, MP, and seconded by The Hon. Oron Joshua Odongo, MP.

MIN. NO. NA/DC-H/2026/115: ANY OTHER BUSINESS

There was no other business arising

MIN. NO. NA/DC-H/2026/116: ADJOURNMENT

There being no other business, the meeting was adjourned at 1pm.

Sign..... Date.....8/4/2026.....

THE. HON. DR. NYIKAL JAMES WAMBURA, CBS, MP
CHAIRPERSON, DEPARTMENTAL COMMITTEE ON HEALTH

COPY OF THE NEWSPAPER ADVERTISEMENT ON PUBLIC PARTICIPATION ON THE

BILL

Chaos as ex-DP's allies hit out at Ruto and Sakaja

- What was to be a warm welcome for Rigathi Gachagua turned chaotic and violent.
- Gachagua allies hit out at President Ruto and Nairobi Governor Johnson Sakaja.

OKUMU MODACHI, NAIROBI

It was a day full of drama as former Deputy President Rigathi Gachagua jetted back after six weeks tour of the US.

From Jomo Kenyatta International Airport (JKIA) through Mombasa highway, Gachagua's return was punctuated by armed goons who attacked his convoy.

The theatre started at the airport after Gachagua's allies led by DCP deputy leader Cleopas Malala were barred from accessing certain sections. Gachagua touched down aboard Ethiopian Airline a few minutes past noon. Then followed a joyous rapture from his followers as he emerged from his car sunroof.

Some wielded placards with statements praising the impeached DP on his return as they chanted anti-Ruto slogans of "wantam and Kasongo" while playing to the tune of the convoy music.

The crowd had gathered at the airport and sang in joy as their leader acknowledged their welcoming gesture. But the joy lasted just a short while as the crowd faced goons just as the convoy touched Mombasa road.

The youths pelted the convoy with stones, disrupting the celebration among DCP followers. Mombasa Road heading to Capital City of Nairobi, was a field of drama and chaos.

The procession of sleek vehicles and motorcycles was attacked by goons who robbed people of their valuables. Along the highway, the hum of engines and ululations was interrupted by shrill cries, the air charged as teargas were lobbed at the motorcade. As the convoy surged towards General Motors, it emerged that journalists were among those injured while covering the procession.

Citizen TV's videographer sustained head injuries and was rushed to hospital while *KTN* crew was robbed of their car keys, leaving them stranded and terrified as goons threatened them.

"The windows of our vehicle were shattered and goons kept pelting stones at us, holding a knife to a colleague. We are lucky to be alive," said Brian Otieno, a *Standard* reporter.

"They broke the window on second attempt and gained access, demanding that we hand them our belongings. I told them they had taken everything," shared Collins Oduor, a photojournalist with *The Standard*.

The motorcade made a stop near Airtel where the opposition leaders addressed the crowd, castigating President William Ruto of frustrating the welcome, claiming police were deployed to block Gachagua's reception.

"We wanted to receive our party leader but they deployed police officers. They planned to arrest him but we have said no. We want Ruto to respect human rights," said Malala.

Murang'a Senator Joe Nyutu called on the international community to intervene and "rescue the country."

Embaskasi North MP James Gakuya slammed Nairobi Governor Johnson Sakaja, accusing him of hiring goons to disrupt Gachagua's return. "It is a sad day. We are in a democratic country yet we are being attacked as if we are thugs. Sakaja, this is childish character," he said.

omodachi@standardmedia.co.ke

DCP leader Rigathi Gachagua leading his motorcade along Mombasa road after his arrival from the US, yesteday. [Kanyiri Wahito]

HARAMBEE

REPUBLIC OF KENYA

THIRTEENTH PARLIAMENT - FOURTH SESSION (2025)

THE NATIONAL ASSEMBLY

IN THE MATTER OF ARTICLE 118(1) (b) OF THE CONSTITUTION
AND
IN THE MATTER OF CONSIDERATION BY THE NATIONAL ASSEMBLY OF:
a) THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL (NATIONAL ASSEMBLY BILL No. 41 OF 2025); AND
b) THE KENYA JUDICIARY ACADEMY BILL (NATIONAL ASSEMBLY BILL No. 42 of 2025)

INVITATION TO SUBMIT MEMORANDA

WHEREAS, Article 118(1) (b) of the Constitution of Kenya requires Parliament to facilitate public participation and involvement in the legislative and other business of Parliament and its Committees, and National Assembly Standing Order 127(3) requires House Committees considering Bills to facilitate public participation;

AND WHEREAS, the **Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025)** and the **Kenya Judiciary Academy Bill (National Assembly Bill No. 42 of 2025)** were read a First Time on 14th August, 2025 and referred to the relevant Departmental Committees for consideration and reporting to the House;

IT IS NOTIFIED that—

(1)The **Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025)** is sponsored by the **Leader of the Majority Party**, seeking to give effect to Article 43(1)(a) of the Constitution by providing for the responsibility of the national and county governments in the realisation of quality of healthcare for patients; establishment, powers and functions of the Quality Healthcare and Patient Safety Authority; registration, licensing and accreditation of health facilities; and standards for quality of healthcare.

(2)The **Kenya Judiciary Academy Bill (National Assembly Bill No. 42 of 2025)** is sponsored by the **Leader of the Majority Party**, seeking to give effect to Article 172(1)(d) of the Constitution by establishing the Kenya Judiciary Academy which shall be the principal institution responsible for implementing and coordinating the continuing education and training of judges, judicial officers and judicial staff.

NOW THEREFORE, in compliance with Article 118(1)(b) of the Constitution and Standing Order 127(3), the Clerk of the National Assembly hereby invites the public and stakeholders to submit memoranda on the Bills to the Departmental Committees specified below –

Sl/No.	Bill	DEPARTMENTAL COMMITTEE
1.	Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025)	Health
2.	Kenya Judiciary Academy Bill (National Assembly Bill No. 42 of 2025)	Justice and Legal Affairs

Copies of the Bill are available at the National Assembly Table Office, Main Parliament Buildings and on www.parliament.go.ke/the-national-assembly/house-business/bills.

The memoranda may be forwarded to the **Clerk of the National Assembly, P.O. Box 41842-00100, Nairobi**; hand-delivered to the **Office of the Clerk, Main Parliament Buildings, Nairobi**; or emailed to cna@parliament.go.ke to be received on or before **Friday, 5th September 2025 at 5.00 p.m.**

S. NJOROGE, CBS

CLERK OF THE NATIONAL ASSEMBLY

22nd August 2025

"For the Welfare of Society and the just Government of the People"

LETTER INVITING STAKEHOLDERS TO SUBMIT VIEWS ON THE BILL

THE NATIONAL ASSEMBLY
OFFICE OF THE CLERK

P. O. Box 41842-00100
Nairobi, Kenya
Main Parliament Buildings

Telephone: +254202848000 ext. 3300
Email: cna@parliament.go.ke
www.parliament.go.ke/the-national-assembly

When replying, please quote

Ref: NA/DDC/DC-H/2025/99 **22nd October,2025**

Hon. Aden Barre Duale, EGH
Cabinet Secretary
Ministry of Health
Afya House
NAIROBI

Dr. Oluga Fredrick Ouma, OGW
Principal Secretary
State Department for Medical Services
Ministry of Health
Afya House
NAIROBI

Ms. Mary Muthoni Muriuki, CBS
Principal Secretary
State Department for Public Health and Professional Standards
Ministry of Health
Afya House
NAIROBI

Hon. Shadrack J. Mose,
Solicitor General of the Republic of Kenya
Sheria House, Harambee Avenue
P.O. Box 40112- 00100
NAIROBI

Mr. Peter Musyimi, HSC
Ag. Chief Executive Officer/ Commission Secretary
Kenya Law Reform Commission (K.L.R.C)
Reinsurance Plaza, 3rd Floor
Taifa road
P.O BOX 34999-00100
NAIROBI

Dr. David G. Kariuki
Chief Executive Officer
Kenya Medical Practitioners and Dentists Council
KMP&DC House, Woodlands Rd, Off Lenana Road
P. O. Box 44839-00100
NAIROBI

Mr. Ibrahim Wako
Chief Executive Officer
Kenya Clinical Officers Council,
P. O. Box 19795
Blueviolet Plaza along Kindaruma road
NAIROBI

Dr. Kioko Jackson
Chief Executive Officer
The Kenya Health Professions Oversight Authority (KHPOA)
11th Floor, KWFT Building,
Masaba Rd, Upper Hill,
P.O. Box 34422 – 00100
NAIROBI

Ms. Anne N. Mukuna
Ag. Chief Executive Officer
The Nursing Council of Kenya (NCK)
NCK Plaza, Kabarnet Road off Ngong Road
P.O. Box 20056-00200
NAIROBI

Dr. Davji Bhimji Atellah
Chief Executive Officer /Secretary General
Kenya Medical Practitioners, Pharmacists, and Dentists Union (KMPDU)
Blue Violets Plaza
5th Floor – Suite 506, Kindaruma Lane
P.O. BOX 157 – 00202 KNH,
NAIROBI

Dear Hon Duale

RE: STAKEHOLDER ENGAGEMENT BY THE DEPARTMENTAL COMMITTEE ON HEALTH ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)

The Departmental Committee on Health is established pursuant to Standing Order 216 and is mandated *inter alia* '***to study and review all legislation referred to it'.***

Pursuant to the provisions of Standing Order 127(1), the **Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025)**, was committed to the Committee for consideration.

Copies of the Bill are available at the **National Assembly Table Office, Main Parliament Buildings,** and on www.parliament.go.ke/the-national-assembly/house-business/bills

In line with the above mandate and in compliance with the provisions of Article 118 (1) (b) of the Constitution, the Committee, during its sitting held on **Tuesday, 14th October, 2025**, resolved to invite you for deliberations on the Bill. The Meeting is scheduled for **Wednesday, 28th October 2025, at 10.00 am, at a venue to be communicated within parliament Buildings.**

Kindly provide fifteen (15) copies of your submission and send a soft copy to the Office of the Clerk via email: cna@parliament.go.ke. In your submission, please indicate the specific clause(s) of the Bill, your proposed amendment(s), and the justification for each proposal

The Liaison Officer for this meeting is Mr.Hassan A. Arale, Committee Clerk, who may be contacted on **Tel No. 0721480578 or** email: ddc@parliament.go.ke

Yours

JEREMIAH W. NDOMBI, MBS
For: CLERK OF THE NATIONAL ASSEMBLY

Copy to: **Hon. Dorcas A. Oduor, SC, OGW, EBS**
Attorney General of the Republic of Kenya
Office of the Attorney General and Department of Justice
Sheria house
Harambee Avenue
NAIROBI

CPA. Dr. Aurelia C. Rono, CBS
Principal Secretary
State Department for Parliamentary Affairs
Railway Building
Haile Selassie Avenue
NAIROBI

Hon. Ichung'wah, Anthony Kimani
Leader of the Majority Party
Parliament Buildings
NAIROBI

LETTER INVITING STAKEHOLDERS FOR A MEETING WITH THE COMMITTEE ON THE

BILL

THE NATIONAL ASSEMBLY
OFFICE OF THE CLERK

P. O. Box 41842-00100
Nairobi, Kenya
Main Parliament Buildings

Telephone: +254202848000 ext. 3300
Email: cna@parliament.go.ke
www.parliament.go.ke/the-national-assembly

When replying, please quote
Ref. NA/DDC/DC-H/2025/87

25th September, 2025

Hon. Aden Barre Duale, EGH
Cabinet Secretary
Ministry of Health
Afya House
NAIROBI

Dr. Oluga Fredrick Ouma, OGW
Principal Secretary
State Department for Medical Services
Ministry of Health
Afya House
NAIROBI.

Ms. Mary Muthoni Muriuki, CBS
Principal Secretary
State Department for Public Health and Professional Standards
Ministry of Health
Afya House
NAIROBI

Dr. David G. Kariuki
Chief Executive Officer
Kenya Medical Practitioners and Dentists Council,
KMP&DC House, Woodlands Rd, Off Lenana Road
P. O. Box 44839-00100
NAIROBI

Hon. Shadrack J. Mose, CBS
Solicitor General
Office of the Attorney General &
Department of Justice
Sheria House, Harambee Avenue
NAIROBI

Mr. Peter Musyimi
Ag. Commission Secretary
Kenya Law Reform Commission
3rd Floor, Reinsurance Plaza, Taifa Road,
NAIROBI

Dear Dr. Aluga,

RE: MEETING WITH THE DEPARTMENTAL COMMITTEE ON HEALTH ON THE CONSIDERATION OF BILLS

The Departmental Committee on Health is established pursuant to Standing Order No. 216 of the National Assembly and mandated to, among other things, ***study and review all legislation referred to it.***

In line with the provisions of Standing Order 127(1), the following two Bills and one legislative proposal has been committed to the Committee for consideration:

1) **The Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025),** sponsored by the Leader of the Majority Party **Hon. Kimani Ichung'wah, EGH, MP**. The Bill seeks to give effect to Article 43(1) (a) of the Constitution on access to healthcare.

2) **The Health (Amendment) Bill, 2024,** sponsored by the **Hon. Jane Njeri Maina, MP.** This Bill seeks to amend the Health Act to provide for access to emergency treatment and healthcare services prior to the payment of prospective medical cost by users.

3) **The Medical Practitioners and Dentists (Amendment) Bill, 2024,** sponsored by the **Hon. Duncan Maina Mathenge, M.P**. The legislative proposal seeks amendments to the Medical Practitioners and Dentists Act (Cap. 253).

Pursuant to Article 118(1) (b) of the Constitution and Standing Order 127(3) of the National Assembly, the Committee resolved to invite you to submit views and comments on the said Bills.

Accordingly, you are kindly requested to submit written comments on the Bills. In view of the strict timelines within which the Committee must complete its scrutiny, **the Committee would be obliged if your comments are received on or before Monday, 6th October, 2025.**

Further, you are invited to appear before the Committee to present your views and comments in a meeting scheduled for **Tuesday, 7th October, 2025, at 10:00 a.m., in Committee Room 12, Parliament Buildings.**

Our Liaison Officer on this subject are **Mr. Hassan A. Arale, Committee Clerk,** who may be contacted on **Tel. No. 0721480578** or email: **ddc@parliament.go.ke.**

Yours Sincerely,

PETER K CHEMWENO
For: CLERK OF THE NATIONAL ASSEMBLY

Copy to: **Hon. Dorcas Oduor, OGW, EBS**
Attorney General
Office of the Attorney General &
Department of Justice
Sheria House, Harambee Avenue
NAIROBI

Hon. Kimani Ichung'wah, EGH, MP
Kikuyu Constituency
Parliament Buildings
NAIROBI

Hon. Jane Njeri Maina, MP.
Kirinyaga Constituency
Parliament Buildings
NAIROBI

THE NATIONAL ASSEMBLY
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When replying, please quote

REF: NA/DDC/DC-H/2026/15

10th March, 2026

Dr. Oluga Fredrick Ouma, OGW
Principal Secretary
State Department for Medical Services
Ministry of Health
Afya House
NAIROBI.

Ms. Mary Muthoni Muriuki, CBS
Principal Secretary
State Department for Public Health and Professional Standards
Ministry of Health
Afya House
NAIROBI

Dr. Mercy Mwangangi
Chief Executive Officer
Social Health Authority
Community Area
NAIROBI

Mr. Anthony Lenaiyara
Ag. Chief Executive Officer
Digital Health Agency
Community Area
NAIROBI

Dr. David G. Kariuki
Chief Executive Officer,
Kenya Medical Practitioners and Dentists Council,
Woodlands Rd, off Lenana Road
P.O. Box 44839-00100
NAIROBI

Dear Dr Oluga

RE: RETREAT WITH THE DEPARTMENTAL COMMITTEE ON HEALTH TO DELIBERATIONS ON THE IMPLEMENTATION OF UNIVERSAL HEALTH COVERAGE (UHC), TRANSITION TO THE SOCIAL HEALTH AUTHORITY (SHA), AND CONSIDERATION OF PENDING HEALTH BILLS

The Departmental Committee on Health is mandated pursuant to National Assembly Standing Orders 216 part (5) (b) to ***"study the programme and policy objectives of ministries and departments and the effectiveness of the implementation".***

In line with this mandate, the Committee, during its Sitting held on **Thursday, 12th February 2026,** resolved to hold a retreat with key health sector agencies to deliberate on operational matters concerning the implementation of Universal Health Coverage (UHC) and the transition to the Social Health Authority (SHA). The deliberations will specifically focus on the operations of the Social Health Authority (SHA) and the Digital Health Agency (DHA). **The list of specific issues for deliberations during the meeting is attached.**

Further, the Committee is currently considering the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025) sponsored by the Leader of the Majority Party and the Harm Reduction Bill (National Assembly Bill No. 37 of 2025) sponsored by Hon. Esther Muthoni Passaris, MP.

Pursuant to Article 118(1) (b) of the Constitution and Standing Order 127(3) of the National Assembly, the Committee resolved to invite the Ministry of Health, as a key stakeholder, to submit its views and comments on the said Bills.

Accordingly, the purpose of this letter is to invite the two Principal Secretaries and the Chief Executive Officers of the Social Health Authority, the Digital Health Agency and the Kenya Medical Practitioners and Dentists Council to attend a retreat with the Committee scheduled for **Wednesday, 18th March 2026 and Thursday, 19th March 2026 in Mombasa County** to deliberate on the above matters.

The specific venue will be communicated in due course.

You are requested to bring (15) physical copies of your submissions during the meeting and send electronic copies to the Office of the Clerk of the National Assembly via email address: cna@parliament.go.ke by **Monday, 16th March, 2026.**

The Liaison Officers for this meeting are **Mr. Adan Gindicha,** Head of Department (Social Sector) who may be contacted on **Tel No. 0720450112** or email: **adan.gindicha@parliament.go.ke** and **Ms. Gladys Kiprotich,** Clerk Assistant, who may be contacted on **Tel. No. 0718721253** and gladys.kiprotich@parliament.go.ke

Yours

JEREMIAH NDOMBI, MBS
For: CLERK OF THE NATIONAL ASSEMBLY

Copy to: **Hon. Aden Barre Duale, E.G.H**
Cabinet Secretary
Ministry of Health
Afya House.
NAIROBI

Dr. Mohammed Abdi
Chairperson
Social Health Authority
SHA Building, Ragati Road
Community Area
NAIROBI

Mr. Silas Simatwo
Chairman, Board of Directors
Digital Health Agency
9th Floor, Social Health Authority (SHA) Building
Community Area
NAIROBI

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When replying, please quote
REF: NA/DDC/DC-H/2026/17

16th March, 2026

Dr. Jackson Kioko
Chief Executive Officer,
Kenya Health Professions Oversight Authority (KHPOA)
KMPDC building - 3rd Floor
P.O. BOX 34422 - 00100
NAIROBI

Mr. Ibrahim Wako
Registrar/Chief Executive Officer
Clinical Officers Council (COC)
Blue Violet Plaza, 2nd Floor, on Kindaruma Road, off Ngong Road, Nairobi
P.O Box 19795 - K.N.H
NAIROBI

Mr. Patrick Kisabei
Registrar/Chief Executive Officer,
Kenya Medical Laboratory Technicians and Technologists Board
ACK Garden House, 4th Floor, 1st Ngong Avenue, Nairobi.
P.O. Box 20889 – 00202
NAIROBI

Dear Mr Wako

RE: RETREAT WITH THE DEPARTMENTAL COMMITTEE ON HEALTH TO CONSIDER THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL (NATIONAL ASSEMBLY BILL NO. 41 OF 2025) SPONSORED BY THE LEADER OF THE MAJORITY PARTY

This is further to the telephone conversations held between yourselves and the Chairman of the Departmental Committee on Health on Friday, 13th March 2026.

The Committee has resolved to invite you to its retreat in **Mombasa County** on **Thursday, 19th March 2026, at 9.00 a.m**, to make a presentation on the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025), sponsored by the Leader of the Majority Party. The meeting will take place at the Sarova Whitesands Resort.

The Liaison Officers for this meeting are **Mr. Adan Gindicha, Head of Department** (Social Sector),who may be contacted **on Tel No. 0720450112** or email: adan.gindicha@parliament.go.ke, and **Ms. Gladys Kiprotich, Clerk Assistant,** who may be contacted on **Tel. No. 0718721253** and gladys.kiprotich@parliament.go.ke

Yours

JEREMIAH W. NDOMBI, MBS
For: CLERK OF THE NATIONAL ASSEMBLY

STAKEHOLDER SUBMISSIONS

REPUBLIC OF KENYA

MINISTRY OF HEALTH
OFFICE OF THE CABINET SECRETARY

STATEMENT BY THE CABINET SECRETARY FOR HEALTH TO THE NATIONAL ASSEMBLY STANDING COMMITTEE ON HEALTH ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

Honourable Chairperson and Honourable Members of the Committee,

We acknowledge receipt of the letter dated 25th September 2025 referenced NA/DDC/DC-H/2025/87 requesting for written submissions on the Quality Healthcare and Patient Safety Bill as well as to appear before the Committee to present views and comments today.

Honourable Members, Article 43 of the Constitution enshrines every individual's entitlement to the highest attainable standard of health, encompassing access to healthcare services, including reproductive health, and guarantees emergency medical treatment.

Honourable Members, Article 21(2) mandates the State to take legislative, policy and other measures, including the setting of standards, to achieve the progressive realisation of the right to the highest attainable standard of health. These constitutional provisions have elevated public expectations for improved quality in health service delivery.

Honourable Members, the Government is undertaking legal reforms intended to provide the legislative basis for the realization of Universal Health Coverage (UHC), including through the enactment of:

a) The Primary Healthcare Act (No. 13 of 2023);

b) The Digital Health Act (No. 15 of 2023);

c) The Facility Improvement Financing Act (No. 14 of 2023); and

d) The Social Health Insurance Act (No. 16 of 2023).

Honourable Members, despite these progressive frameworks, a significant gap exists in the provision of quality healthcare services and the protection of the safety of patients, which are a critical determinant of the overall health and well-being of a nation's population.

Honourable Members, we call upon this Honourable Committee to note that, as a country, we have never had a national body responsible for quality healthcare and patient safety. This gap has led to inconsistencies in the quality of healthcare services provided and has resulted in various regulatory bodies independently setting standards for health facilities within their respective mandate, resulting in a fragmented system with no overarching oversight and weak enforcement mechanisms. For instance, the Kenya Medical Practitioners and Dentists Council, Clinical Officers Council, Kenya Medical Laboratory Technicians and Technologists Board, and the Nursing Council of Kenya all operate independently in regulating healthcare institutions. This fragmented regulatory framework leads to inconsistent standards, and accountability gaps, ultimately compromising patient safety and quality of healthcare services.

Honourable Members, there has also been a significant conflict of interest within our healthcare system, whereby the same regulatory bodies that register and license health facilities are also tasked with registering and licensing the health professionals who manage those facilities. As a true testament to the principle that *one cannot be the judge, jury, and executioner*, the concentration of this unchecked regulatory authority has contributed to the proliferation of rogue health institutions and the misclassification of facilities which, ultimately, undermines patient safety and the delivery of quality healthcare services. This misclassification has, for instance, seen a health facility that is essentially a Level 2 facility based on the services it offers, fraudulently designated as Level 3, or a Level 3 designated as a Level 4, resulting in mismatched accreditation under the

Social Health Authority (SHA), and ultimately distorting service delivery, and facilitating payment of fraudulent reimbursement claims.

Honourable Members, international best practice dictates a clear separation between the regulation of health professionals and the regulation of health facilities to ensure accountability, impartiality, and effectiveness in oversight.

Honourable Members, the current fragmented regulatory framework has left some healthcare services unregulated. For instance, there are currently no nationally recognized standards for ambulance services, which poses risks to patient safety, quality of healthcare, and coordination during medical emergencies.

Additionally, the fragmentation in the health sector has led to significant gaps in the oversight of emerging healthcare practices and procedures. As a result, new services often operate in regulatory grey areas, exposing patients and providers to legal uncertainty and potential harm. This regulatory vacuum undermines the ability of existing institutions to provide consistent guidance or recourse when disputes arise.

The presence of multiple regulators overseeing different aspects of healthcare facilities has also made the regulatory environment costly, uncoordinated, and inefficient. Health service providers are often required to obtain multiple licenses from different regulatory bodies, each with their own compliance requirements, timelines, and attendant costs. This fragmented approach results in increased administrative burden and compliance costs for healthcare providers which are ultimately passed on to consumers in the form of increased healthcare charges. These inefficiencies undermine the ease of doing business in the health sector and lead to increase in the cost of healthcare services.

Honourable Members, the inadequate regulation and oversight have led to preventable medical errors, poor patient experiences, and suboptimal health outcomes. As a result, there is growing recognition of the need to institutionalize quality and patient safety across all levels of the healthcare system.

Honourable Members, in order to promote streamlined regulation of the health sector, consistency in quality, enhanced accountability and patient safety across the healthcare system, there was need to develop the Quality Healthcare and Patient Safety Bill which seeks to establish a globally-acceptable concept of a national entity with the mandate to set, monitor, and enforce healthcare standards at all levels of care. This will strengthen the quality assurance framework and support Kenya's efforts towards achieving Universal Health Coverage by establishing a centralized regulatory authority to ensure that all healthcare practices including newly introduced procedures and services are subject to clear, consistent, and enforceable standards.

Honourable Members, the Bill also seeks to introduce the concept of "accreditation of health facilities" in accordance with the globally accepted best practice by setting national quality of care accreditation standards which will guide the proposed Quality Healthcare and Patient Safety Authority in the accreditation of health facilities. These standards play a vital role in promoting quality of healthcare and safeguarding patient rights. They guide the systematic evaluation of facilities against established benchmarks related to service delivery, governance, and patient safety. By ensuring adherence to these standards, accreditation enhances the credibility, efficiency, and accountability of health services, thereby contributing to improved health outcomes and public trust in the system.

Honourable Members, the concept and practice of "accreditation" already exists in the country. However, it is not applied in a uniform manner across sectors. Instead, different industries and professions have developed their own accreditation frameworks, each with distinct standards, processes, and outcomes. Within our healthcare system, there are pockets of accreditation carried out by different professional regulators which prescribe different standards for health facilities resulting in a lack of uniformity in accreditation.

Honourable Members, we note that the concept of accreditation has come to be widely associated with the Kenya Accreditation Service (KENAS) which, as provided under the Kenya Accreditation Service Act (Cap. 496A), 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), SafeCare 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.

Honourable Members, from the above, it is evident that 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. As demonstrated by internationally recognized best practice, 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.

Honourable Members, one of the primary functions of accreditation is to institutionalize continuous quality improvement (CQI) within the healthcare system. Health facilities certified by the proposed Quality Healthcare and Patient Safety Authority are required to adhere to evidence-based clinical protocols, maintain adequate infrastructure, and provide safe and effective care. This not only reduces medical errors and adverse events but also improves treatment outcomes and overall patient satisfaction. The process of accreditation also empowers patients to make informed choices by providing them with reliable information about the quality of services across facilities. This fosters public trust locally and internationally in the health system and increases demand for services that meet acceptable standards.

From the perspective of patient rights, accreditation also supports the enforcement of key principles such as informed consent, confidentiality, dignity, non-discrimination, and the right to timely and appropriate care.

Honourable Members, in developing this Bill, we drew upon best practices and conducted extensive stakeholder engagements and public participation across all 47 Counties, in line with Article 10 of the Constitution. Key stakeholders and members of the public were granted the opportunity to submit comments, views, and representations on the Bill. We carefully reviewed the feedback received and amended the Bill, where appropriate, to ensure that it accurately reflects the needs and expectations of our society.

Honourable Members, it is also evident that there has been a gap in the uniform regulation of healthcare, which has created room for the entry and practice of quacks. This lack of consistency in regulation has allowed unqualified individuals and unauthorized health facilities to operate within the health sector, often without oversight or accountability. The presence of such quacks undermines patient safety, exposes the public to preventable harm, erodes trust in the health system, and compromises the quality of care and patient safety delivered to citizens.

Honourable Members, the proposed Bill seeks to address these challenges by creating a unified regulatory system for the oversight, registration, licensing and accreditation of health facilities, thereby promoting consistency, accountability, and improved healthcare outcomes. It also seeks to establish a unified health sector tribunal to harmonize dispute resolution within the health sector and to serve as a platform to interpret and adjudicate on emerging health issues, thereby reinforcing oversight, fostering innovation within a regulated framework, and safeguarding the rights of all stakeholders.

Honourable Members, kindly allow me to highlight the Clauses of the proposed Bill as follows:

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

Honourable Members, Clauses 7- 25 outlines the rights of patients who seek healthcare services from a health facility. These rights are to be read with those provided for under the Health Act, Cap. 241. The rights include right to safe and quality care, right to timely and effective care, right to safe and accessible health facilities, right to safe processes and practices, right to care by a qualified health professional, right to dignity and equity, right to information and decision making, right to be heard and right to safe and quality health products and technologies.

Honourable Members, Clauses 26-41 provides for the establishment of the Authority as the primary regulator of health facilities for purposes of quality of healthcare, its functions, powers; the composition, term of office, functions and qualifications of the Board of Directors of the Authority. It further provides for the appointment of a Chief Executive Officer and the staff of the Authority.

Honourable Members, Clauses 42-71 provides for the process of registration, licensing and accreditation of health facilities including timelines and prerequisites for grant of certificates for registration, licencing and accreditation, the validity period and instances where the Authority can order suspension or revocation of the certificates. It also provides for consequences of operating health facilities which are not registered or licensed. It sets out the quality improvement in a

health facility, the procedure for quality scoring and rating, award of performance rating and monitoring of compliance by the Authority.

Honourable Members, Clauses 72-82 provides for the conduct of inspections and investigations by the Authority including the qualifications and powers of inspectors.

Honourable Members, Clauses 83-86 provides for the establishment of a Health Care Tribunal, its composition and its role in adjudicating disputes arising out of matters envisaged by the Bill and the administration and enforcement of disputes in the health sector once it is enacted.

Honourable Members, Clauses 87-92 provides the sources of funds of the Authority, the modalities on annual reporting by the Authority and handling of the accounts of the Authority including the audit of its finances.

Honourable Members, Clauses 93-100 provides for the delegation of power to the Cabinet Secretary in the Ministry responsible for health, in consultation with the Board of Directors of the Authority, to make regulations for the better carrying into effect of the provisions of the Act and the general provisions such as categorization of ambulances, right of review of a decision and appeal, offences and penalties and the transitional provisions in relation to the registration existing health facilities as well as consequential amendments to other statutes in light of the introduction of this Bill.

Honourable Members, the First Schedule provides for the conduct of the business and affairs of the Board of the Authority.

Honourable Members, the Second Schedule provides the consequential amendments.

Honourable Members, I therefore wish to request the Hon. Members to support the Bill so that we can have a framework for the regulation of quality healthcare and the realization of patient rights and safety.

Thank you. God Bless Kenya.

HON ADEN DUALE, E.G.H
CABINET SECRETARY

REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY
TECHNICIANS & TECHNOLOGIST BOARD
Make Testing a Safe Routine

REF: KMLTTB/NA/71/VOL.1/11 **18th March, 2026**

The Clerk,
National Assembly,
Main Parliament Buildings,
P.O Box 41842 – 00100
NAIROBI.

Dear Sir,

RE: MEMORANDUM ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILL NO. 41 OF 2025)

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a body corporate with statutory mandate to exercise general supervision and control over the training, practice, business and employment of medical laboratory technicians and technologists under Cap 253A Laws of Kenya. The Board also advises the Government in relations to all aspects thereof including validation of invitro diagnostics through Legal Notice NO.113 of 2011.

Reference is made to your letter Ref: NA/DDC/DC-H/2026/17 dated 16th March, 2026 refers.

In summary, the Memorandum highlights the following critical concerns:

1. The Bill impermissibly attempts to separate the profession, the professional and the service – an impossibility in medical laboratory practice, where professional practice, professional service and quality of service are inextricably linked.
2. The proposed amendments fundamentally contradict the spirit, object and purpose of the MLTT Act which envisaged self-regulation by MLS professionals in terms of themselves, the environment and their tools of trade and all other medical professional related facets.
3. The gains the Board has made over the last 26 years in establishing a robust, specialized regulatory framework that safeguards public health would be erased.

4. Medical laboratory facility standards are best understood and enforced by medical laboratory professionals; inspection by non-professionals would create an operational nightmare and compromise service quality.
5. The regulation of medical laboratory reagents and equipment under the new Authority would reduce medical laboratory professionals to mere spectators, stripping them of professional responsibility and accountability for the quality of test results and investigations.

We respectfully request that the attached Memorandum be formally tabled before the Honourable House and given due consideration during the Committee Stage of the Bill.

We trust that this letter and the enclosed Memorandum adequately convey the Board's position and look forward to the House's favourable consideration.

Consequently, the Board unequivocally rejects the Quality Healthcare and Patient Safety Bill, 2025 and all its proposed amendments to the Medical Laboratory Technicians and Technologists Act (Cap. 253A).

Thank you.

Yours Sincerely,

Patrick Kisabei
Ag. Registrar – KMLTTB

CC – Chairman
Parliamentary Committee on Health

KENYA LAW REFORM COMMISSION

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NAIROBI, KE

When replying please quote

Ref. No. KLRC/8/64 VOL. V/(33).
and Date

7th October, 2025 .....20.....

The Clerk
Clerk's Chambers
National Assembly
Parliament Building
P.O. Box 41842 00100
NAIROBI

(Attn: Mr. Peter K Chemweno)

RE: MEETING WITH THE DEPARTMENTAL COMMITTEE ON HEALTH ON THE CONSIDERATION OF BILLS

Please refer to the above subject and your letter Ref.NA/DDC/DC-H/2025/87 dated 25th September, 2025.

Enclosed herewith, please find the Commission's comments.

We thank you for your cooperation and support.

Peter Musyimi, HSC
Ag. SECRETARY/CEO

Encls.

Copy to:

Hon. Dorcas Agik Oduor, SC, OGW, EBS
The Attorney-General
Office of the Attorney-General &
Department of Justice
Attorney General's Chambers
NAIROBI

Hon. Kimani IChung'wah, EGH, Mp
Kikuyu Constituency
Parliament Building
NAIROBI

Hon. Jane Njeri Maina, MP
Kirinyaga Constituency
Parliament Building
NAIROBI

COMMENTS ON THE QUALITY OF HEALTHCARE AND PATIENT SAFETY BILL, (NATIONAL ASSEMBLY BILL NO. 41 OF 2025), THE MEDICAL PRACTITIONERS AND DENTISTS(AMENDMENT) BILL, 2024 AND THE HEALTH (AMENDMENT) BILL, 2024

A. INTRODUCTION

The Kenya Law Reform Commission, (KLRC) is a state corporation established under the Kenya Law Reform Commission Act, Cap. 3 of the laws of Kenya. KLRC has both constitutional and statutory mandate under Section 5(6)(b) of the Sixth Schedule to the Constitution, the Kenya Law Reform Commission Act and the County governments Act, respectively.

The core mandate of KLRC is to review all the laws and recommend for their reform to ensure that the law conforms to the letter and spirit of the Constitution, taking into account the socio-economic, political and technological developments.

Vide a letter dated 25th September, 2025 and received on 1st October, 2025 referenced as NA/DDC/DC-H/2025/87, the KLRC received a request from the Clerk of the National Assembly, to submit comments on the Quality of Healthcare and Patient Safety Bill, (National Assembly Bill No. 41 of 2025), the Medical Practitioners and Dentists(Amendment) Bill, 2024 and the Health (Amendment) Bill, 2024.

Against this background and pursuant to the KLRC's constitutional and statutory mandate, the KLRC makes the following observations—

B. SPECIFIC COMMENTS

I. Quality of Healthcare and Patient Safety Bill, (National Assembly Bill No. 41 of 2025)

KLRC having previously been involved in the development of the Bill, concurs with it, in both form and content. It is a historic legislative effort intended to institutionalize healthcare quality in Kenya. Quality of healthcare remains uneven, fragmented, and poorly regulated. It aims to transform health service delivery by embedding quality, safety, and accountability into the healthcare system ensuring that access to care is not only universal, but also effective, safe, and patient-centered.

II. The Medical Practitioners and Dentists(Amendment) Bill, 2024

The Bill, introduced by Hon. Duncan Maina Mathenge, MP, seeks to amend the Medical Practitioners and Dentists Act (Cap 253) to expand the regulatory scope of the Kenya Medical Practitioners and Dentists Council (KMPDC) which is proposed to be rebranded to "Medical and Dental Council of Kenya" (MDCK) and provide for the regulation of community oral health officers (COHOs), dental technologists, optometrists, and theater technicians. It also aims to facilitate registration of foreign practitioners who are resident in Kenya, strengthen anti-fraud measures in licensing by modernizing licensing procedures.

Support for key provisions

KLRC is of the view that the Bill takes a progressive step toward modernizing healthcare regulation in Kenya, where fragmented oversight has fueled fraud and uneven implementation of standards. More specifically, including COHOs, dental technologists, optometrists and theater technicians under KPMDC will standardize training, registration, and ethical practice for these professions, which are vital for preventive care, surgical support, and diagnostics, aligning with the Ministry of Health's recognition of emerging health roles and addressing rural healthcare gaps.

Concerns and Areas for Improvement

Our concerns and proposed amendments are as follows:

(a) Repetitive enumeration and redundant sections

- The Bill repeatedly lists "community oral health officers, dental technologists, optometrists, and theater technicians" across multiple sections (e.g., Sections 3, 5, 6A–6D, 9, 10, 11B) for uniform regulatory provisions (e.g., registration, licensing, discipline).
- Sections 6A to 6D, which outline registration for these professions, are nearly identical, differing only in profession names and minor requirements (e.g., internship for COHOs). This redundancy bloats the Bill, reduces readability, and complicates future amendments, especially as Kenya recognizes 25 emerging health roles (e.g., radiographers, physiotherapists).

Proposal:

We propose the term "allied health worker" adopted as a collective descriptor, as used in jurisdictions such as Singapore (Allied Health Professions Act, 2011) and the UK (Health and Social Care (Safety and Quality) Act, 2015 which embraces a collective term- "health and social care professions"), to streamline the Bill and future-proof it for additional cadres.

Consequently, merge Sections 6A to 6D into a single provision, listing professions and their requirements in a Schedule, allowing MDCK to add new cadres via Gazette notice, as seen in South Africa's Health Professions Act, 1974. This reduces redundancy, enhances clarity, and enables scalability without legislative amendments.

Recommended Amendments:

i. Amend Section 2: Add:

"'Allied health worker' means a person registered under this Act to practice a profession listed in Schedule 1."

ii. Replace Sections 6A–6D with new Section 6A:

6A. Registration of allied health workers.

(1) A person may apply for registration as an allied health worker in a profession listed in Schedule 1 where the person —

(a) holds a certificate, diploma, higher diploma, or degree, as

specified in Schedule 1, from a university or college recognized in Kenya;

(b) provides proof of internship completion, for professions requiring internship as specified in Schedule 1,; and

(c) satisfies the Council of good moral standing,

(2) Applications shall be in the prescribed form and accompanied by the prescribed fees.

(3) The Council shall register an applicant if satisfied that they are duly qualified and fit to be registered.

(4) The Council may, with Cabinet Secretary approval, amend Schedule 1 by Gazette notice to include additional allied health professions, aligned with national health policy.

iii. SCHEDULE 1: ALLIED HEALTH PROFESSIONS

Profession	Minimum Qualification
1. Community Oral Health Officer	Diploma or Degree
2. Dental Technologist	Diploma or Higher Diploma
3. Optometrist	Diploma, Higher Diploma, or Degree
4. Theater Technician	Certificate or Diploma

(b) Restrictive citizenship requirement

The proposed section 6A–6D limit registration to Kenyan citizens, unlike provisions for other Kenyan professional laws (e.g., Advocates Act, Accountants Act), where

citizenship is relevant only for work permits. This may conflict with EAC mutual recognition agreements, limiting talent mobility amid workforce shortages.

Proposal: Delete the citizenship requirement in the proposed Section 6A-D, aligning with broader professional registration practices.

(c) Prohibitive pre-registration examination

Section 6E mandates a pre-registration examination for all practitioners, including those trained in accredited institutions with completed internships. This is overly restrictive and could create barriers, particularly in underserved areas.

Proposal: Delete Section 6E, as accredited training and internships suffice for registration. This removes unnecessary hurdles for qualified graduates.

(d) Transitional provisions.

Insert a provision requiring persons practicing as allied health workers prior to this Act's commencement to apply for registration within (e.g., 24 months), with exemptions for those meeting equivalent standards.

The Medical Practitioners and Dentists (Amendment) Bill, 2024, has the potential to enhance healthcare quality and accessibility in Kenya. We support its passage but urge the adoption of the proposed amendments to streamline drafting, remove restrictive barriers, and ensure effective implementation.

III. The Health (Amendment) Bill, 2024

KLRC wishes to draw the committee's attention to our submissions on the Health (Amendment) Bill, 2024, referenced KLRC/8/64 VOL. V/(23) and dated 20th August, 2025. We made submissions on the same before the Committee. The submissions are attached herewith for your reference.

C. Conclusion

Subject to the above recommendations, KLRC has no objection to the Bills' enactment.

We conclude by stating that we are committed to ensuring that legislation is developed to the highest standards possible to promote their legal effectiveness and aligns to the current political and socio-economic realities.

COMMENTS TO THE HEALTH (AMENDMENT) BILL,2024

1. Legislative Proposal

Hon. Njeri Maina, MP, has proposed an amendment to the Health Act (Cap. 241) to guarantee access to emergency treatment and other health services without requiring upfront payment of prospective medical costs. The proposal also seeks to criminalise the detention of a deceased person's body by public healthcare facilities as a means of enforcing settlement of outstanding medical bills.

2. KLRC Support for the Proposal

The Kenya Law Reform Commission supports the proposal as a timely and necessary reform that aligns with the Constitution, particularly Articles 26 (Right to Life), 28 (Human Dignity), and 43(1)(a) (Right to the Highest Attainable Standard of Health).

Hospital detention practices (HDP) — the unlawful detention of patients who are medically cleared for discharge or the withholding of deceased bodies due to unpaid bills — have been documented in both public and private facilities in Kenya. The practice has attracted condemnation for violating fundamental human rights, including the rights to health, dignity, and freedom of movement. The World Health Organization recognises HDP as a serious but underreported global health and human rights concern, especially prevalent in low- and middle-income countries where healthcare costs are largely borne out-of-pocket.

In Kenya, media investigations continue to expose cases of patients denied discharge or bodies withheld as collateral for unpaid fees. Government responses have been mostly informal and reactive, often urging amicable resolutions between hospitals and families without addressing the systemic and socio-economic factors that perpetuate the practice. The absence of a clear legislative framework has allowed HDP to persist, undermining public trust in the health system.

HDP raises grave human rights concerns, contravening the prohibition of torture and cruel, inhuman, or degrading treatment as set out in the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the African Charter on Human and Peoples' Rights. It undermines patient autonomy, entrenches discrimination against economically disadvantaged populations, and deepens social and economic inequalities, disproportionately affecting women, children, and the rural and urban poor.

Kenya requires a clear legislative prohibition of HDP, combined with reforms to strengthen health financing and social protection to reduce out-of-pocket expenditure. The proposed amendments to the Health Act represent a critical step toward upholding constitutional rights, protecting human dignity, and building a fairer health system.

No.	Provision in the Legislative Proposal	KLRC Comments to the Proposed Provision	Justification
1	Amendment of Section 2 of Cap 241 – Definition of "emergency medical treatment" "emergency medical treatment" means the necessary initial or immediate medical care that is administered to a critically ill or injured person to avert or prevent death, disability, unnecessary morbidity or worsening of a medical situation.	We agree with the proposal.	To align the definition of "emergency medical treatment" with Article 43(2) of the Constitution, ensuring it covers immediate, necessary, and life-saving interventions without prior conditions such as payment guarantees, thereby safeguarding the right to health and life.
2	Amendment of Section 2 of Cap 241 – Inclusion of new definition	KLRC proposes that the Hon. Member considers including the following definition: "detention" means any act of restraining a person from leaving hospital premises, or withholding the body of a deceased person, for non-payment of hospital bills or medical expenses in whole or in part.	To clarify and standardise the scope of "detention" in the context of medical facilities, ensuring alignment with constitutional protections against unlawful deprivation of liberty.

3	Amendment of Section 2 of Cap 241 – Inclusion of new definition Definition of "guarantee"	"guarantee" means an expressed assurance by a person to a health facility that certain facts or conditions are true or will happen, to pay the unpaid hospital bills or medical expenses of a patient.	To clearly define the legal obligation undertaken by a guarantor to preven disputes and improve enforcement.
4	Amendment of Section 2 of Cap 241 – Inclusion of new definition Definition of "health care guarantor"	"health care guarantor" means a person, natural or juridical, who binds himself jointly and severally to pay the unpaid hospital bills or medical/hospitalisation expenses of the patient.	To ensure accountability by defining the party responsible for fulfilling the guarantee and to protect health facilities from non-payment risks.
5.	Amendment of Section 2 of Cap 241 – Inclusion of the following new definitions- Definition of the term "hospital bills" Definition of the term "medical expenses"	"hospital bill" means the amount owing for clinical and ancillary services rendered, charges for room, meals, medical supplies, drugs and medicines, and payments for use of equipment. "medical expenses "means any costs incurred in the prevention or treatment of injury or disease.	To clarify the scope of recoverable costs by health facilities, preventing ambiguity or disputes about what constitutes hospital or medical expenses.
5.	Amendment of Section 2 of Cap 241 – Inclusion of the following new definition- "pre-hospital care" can be defined as the care received by a patient from an emergency medical service before arriving at a hospital	"pre-hospital care" means any medical care received by a patient from an emergency medical service before arriving at a hospital, including any medical care provided at the scene of an injury or illness or during transportation to a health facility.	The definition is introduced to provide clarity on the scope of services considered as pre-hospital care. It ensures that both on-scene emergency interventions and medical assistance provided during transport to a health facility are expressly covered. This promotes consistency in interpretation and aligns the provision with recognized emergency medical service practices.
6.	Amendment of Section 2 of Cap 241 – Inclusion of new definition Definition of "promissory note"	Define as: an unconditional promise made in writing by a patient or the patient's next of kin to the hospital or medical clinic, engaging to pay on demand, or at a fixed or determinable future time, a sum certain in money for any hospital	To provide a clear legal framework for payment commitments to health facilities, facilitating debt recovery while protecting patient rights.

		bill or medical expenses in the course of medical treatment.	
	Amendment of Section 7 of Cap 241- (a) in sub-section(1),by inserting the words,"prior to the payment of prospective medical costs" immediately after the words "medical treatment"	Kindly consider the amendment as follows- Delete the words "prior to the payment of prospective medical costs" and instead use the following phrase- (a) in sub-section (1),by inserting the words,"prior to the payment of any hospital bill or medical expenses" immediately after the words "medical treatment".	The amendment is intended to enhance clarity and precision in the provision. The phrase "prospective medical costs" may be ambiguous and open to varying interpretations, particularly regarding whether it applies to anticipated, estimated, or actual medical expenses. By replacing it with the words "any hospital bill or medical expenses", the provision is aligned with common usage in medical and legal contexts, ensuring certainty and ease of implementation. This also harmonizes the terminology with existing statutory and regulatory language governing medical treatment and related financial obligations.
8.	Amendment of Section 7 of Cap 241- (b) in subsection(2)(a) ,by inserting the words, "including the appropriate or recommended medical care provided at the scene of the injury or illness during transportation to a health facility ,and through to a department responsible for emergency treatment and early patient care" immediately after the word care.	i. Retention of Original Section 7(2)(a)- It is proposed that the original phrase in section 7(2)(a) be retained as follows— "(2) For the purposes of this section, emergency medical treatment shall include— (a) pre-hospital care; ii. Insertion of Definition "pre-hospital care" To enhance clarity, it is further proposed that a definition of "pre-hospital care" be included in the Act as follows— "pre-hospital care" means any medical care received by a patient from an emergency medical service before arriving at a hospital, including any medical care provided at the scene of an injury or illness or during transportation to a health facility.	The retention of the phrase "pre-hospital care" acknowledges the critical role of emergency medical services in saving lives before hospital admission. Including a statutory definition of pre-hospital care ensures uniform understanding and application of the term. Deletion of the phrase "through to a department responsible for emergency treatment" prevents an unduly restrictive interpretation that might exclude other valid forms of emergency medical treatment. Further, the proposal for a dedicated Emergency Medical Care Services Act is informed by the need for a holistic and coordinated legal framework to guarantee timely, equitable, and standardized emergency care services in line with international best practices.

		iii. Deletion of Words in the proposed amendment- It is proposed that the words "through to a department responsible for emergency treatment" be deleted. The deletion is necessary to remove redundancy and avoid limiting the scope of emergency care to hospital-based departments only. Pre-hospital care is an entire framework that goes beyond hospital settings. It encompasses ambulance services and management, regulation and deployment of emergency medical technicians, the role of emergency medical personnel, and overall emergency care management—including the critical role played by bystanders and members of the public in providing first response. Currently, Kenya's legislative framework does not comprehensively recognize or regulate these components of pre-hospital care. This constitutes a significant gap in the health sector's legal and policy environment. Addressing this gap through statutory recognition will ensure that the continuum of emergency care, from the scene of an incident to hospital admission, is clearly provided for in law. Adding this word doesn't sufficiently address this legislative gap.	Recommendation for Comprehensive Legislation Parliament should consider developing a separate Bill, the Emergency Medical Care Services Act, to provide for standardized, unified, and quality-accessible emergency medical care, and for connected purposes. Such a framework law would ensure proper regulation, coordination, and resourcing of emergency medical services across the country.
9.	Amendment of Section 7 of Cap 241- (c) in subsection (2)(b) by deleting the words "the individual and substituting	Consider adding another amendment to the proposal by inserting the following words – (d) in sub-section (2)(b) by deleting the words "the individual and substituting therefor with the following words "	The amendment seeks to broaden the scope of emergency medical treatment under sub-section (2)(b) by expressly recognizing the continuum of care provided to an individual at different stages of an emergency. By inserting the words "including the appropriate medical care provided at the scene of injury or illness during

	therefor with the following words- "a critically ill or injured patient prior to transportation to a definitive health facility"	"a critically ill or injured patient including the appropriate medical care provided at the scene of injury or illness during transportation to a health facility, a department responsible for emergency and early patient care."	transportation to a health facility, a department responsible for emergency and early patient care", the provision ensures clarity that emergency treatment is not confined to hospital-based interventions alone but extends to pre-hospital and early hospital-based care. This clarification is necessary to align the law with practical realities of emergency medical services, which involve immediate response at the scene, care during transportation, and prompt attention at the receiving facility. It further promotes comprehensive protection of the constitutional right to emergency medical treatment under Article 43 of the Constitution of Kenya by guaranteeing access to timely, coordinated, and life-saving interventions at every stage of the emergency care chain.
10.	Amendment of Section 7 of Cap 241- (e) in subsection(2)(c) ,by deleting the words "the victim and substituting therefor with the words "a patient who is critically ill or injured"	We agree with this amendment. The use of the word "victim" is ambiguous and is already defined in another statute, the Victim Protection Act. This proposed amendment will bring statutory harmony with section 9 of the Act which provides as follows— 9. No specified health service may be provided to a patient without the patient's informed consent unless— (d) the patient is being treated in an emergency situation.	The amendment seeks to replace the term "victim" with the more accurate and medically appropriate expression "a patient who is critically ill or injured". The word "victim" is contextually linked to criminal law and justice processes, and its continued use in a health statute creates ambiguity and inconsistency with existing laws such as the Victim Protection Act. The proposed wording reflects the medical nature of emergency treatment, ensures statutory harmony within the Act, and aligns with Section 9 on informed consent in emergency situations. By adopting this language, the provision clearly centers on the patient's health condition rather than their legal or social status, thereby promoting clarity, precision, and uniformity in interpretation.

11.	Amendment of Section 7 of Cap 241- (f) by inserting the following new subsection immediately after subsection(3)- "(4) A person in charge of a public health facility commits an offence ,if the person demands or permits the demand of payment of prospective medical fees or admission fees prior to providing emergency treatment ,and is liable on conviction to a fine not exceeding three million shillings.	The current proposal introduces a new subsection criminalizing demands for upfront medical or admission fees in public health facilities before providing emergency treatment. While this is a positive step, the provision fails to address hospital detention and discriminates against patients in private facilities, where violations are equally prevalent. This proposal must consider the following constitutional contexts, **Article 43(1)(a)** which guarantees that every person the right to the highest attainable standard of health, applicable in both public and private facilities. and **Article 29** which protects individuals from arbitrary detention, including wrongful confinement for unpaid medical bills. Kenyan courts have repeatedly affirmed that hospital detention, ***whether in public or private facilities,*** is unconstitutional: **Gideon Kilundo & Daniel Mwenga v Nairobi Women's Hospital [2018]** – Detaining patients for unpaid bills violates the right to freedom. **Christine Kidha v Nairobi Women's Hospital [2016]** – Detention to compel payment of a contractual obligation undermines liberty. **Tryphosa Jebet Koskey v Elgon View Hospital [2016]** – Hospitals must pursue debt recovery through lawful civil processes. **Tryphosa Jebet Koskey v Elgon View Hospital[2016]elk** where it was held that the hospital could have	The proposed amendment limits protection to public hospitals, leaving patients in private facilities vulnerable to unlawful detention and denial of emergency care. KLRC'S proposal "(4) A health facility that refuses to discharge a patient after medical discharge has been indicated, for reasons of non-payment in part or in full of hospital bills or medical expenses, commits an offence and is liable on conviction to a fine not exceeding three million shillings." Proposes to :- (1) Ensures equal protection of patients' rights across all facilities. (2) Aligns legislation with constitutional provisions and judicial precedents. (3) Encourages lawful debt recovery mechanisms without compromising patient dignity.

		released the petitioner and recovered the outstanding debt as provided by law. The Key issue we have with this proposal id that the proposed amendment limits protection to public hospitals, leaving patients in private facilities vulnerable to unlawful detention and denial of emergency care. <u>Proposed Wording</u> "(4) A health facility that refuses to discharge a patient after medical discharge has been indicated, for reasons of non-payment in part or in full of hospital bills or medical expenses, commits an offence and is liable on conviction to a fine not exceeding three million shillings."	
12.	Amendment of Section 7 of Cap 241- (f) by inserting the following new subsection immediately after subsection(3)- (5) A person in charge of a public health facility commits an offence ,if the person detains or permits the detention of a body of a person for purposes of enforcing settlement of pending bills, and is liable on conviction to a fine not exceeding two million shillings.	Section 7 of the Public Health Act (Cap 241) currently lacks a clear prohibition against the detention of deceased bodies by hospitals due to unsettled medical bills. The proposed amendment seeks to address this gap by criminalizing such practices and ensuring that the dignity of the deceased and their families is protected. <u>*Judicial Precedent*</u> In the case of *Mary Nyang'anyi Nyaigero & Another v Karen Hospital Ltd & Another [2016] eKLR,* the High Court ordered the immediate release of a dead body that had been withheld by the hospital over pending bills. The court held that detaining a body as security for payment is unlawful and violates the dignity of the deceased and the rights of surviving family members.	parliament should adopt the KLRC-proposed wording to ensure a uniform and comprehensive legal framework prohibiting the detention of deceased bodies, strengthen patient and family rights, and uphold constitutional and human dignity standards.This will- (1) Upholds human dignity by preventing the commodification of deceased bodies. (2) Extends protection to both public and private facilities to eliminate discrimination. (3) Aligns statutory law with constitutional rights under Articles 28 (human dignity) and 29 (freedom and security of the person). (4) Reinforces judicial pronouncements that hospitals

		he Kenya Law Reform Commission (KLRC) recommends strengthening the provision to cover all health facilities, not just public ones, and to impose a higher penalty: "A health facility that refuses to release the body or bodies of deceased patients for reasons of non-payment in full or in part of hospital bills or medical expenses commits an offence and is liable on conviction to a fine not exceeding five million shillings."	must pursue lawful civil debt recovery mechanisms rather than detaining bodies.
13.	Section 12 of the Principal Act is amended by inserting the following subsections immediately after Section 12(2)- 2A. All healthcare providers in the public sector shall not demand for prepayment of prospective medical costs as a condition for the provision of emergency treatment to a user.	Section 12 of the Principal Act currently regulates the provision of healthcare services but does not comprehensively prohibit demanding prepayment for emergency medical treatment. The proposed amendment seeks to address this gap by protecting patients in life-threatening situations from denial of urgent care due to financial constraints. The Kenya Law Reform Commission (KLRC) recommends broadening this protection to include all healthcare providers, both public and private, to ensure non-discriminatory access to emergency care: "(2A) A healthcare provider shall not demand prepayment of prospective medical costs as a condition for the provision of emergency treatment to a user."	Parliament should adopt the KLRC-proposed wording to guarantee equal and timely access to emergency medical treatment in both public and private healthcare facilities, ensuring that no life is put at risk due to inability to prepay. The proposed change will- I. Promote access to healthcare services without discrimination based on the type of facility. II. Ensure equality and non discrimination of public facilities. Limiting protection to public facilities undermines constitutional principles of equality under Article 27. III. Promote the realization of the right to health .Requiring upfront payment during emergencies can lead to preventable deaths and violates the duty of care owed by healthcare providers.
14.	New provision Recommendation for the Deletion of Section 12(3)(a) of the Health Act as follows- "Section 12 of the Principal Act is	Section 12(3) of the Health Act, which currently grants the head of a health facility discretionary power to impose conditions on the services provided by healthcare professionals based on their own personal judgement as opposed to the law. The provision has been prone to	If Section 12(3)(a) remains, the following risks persist: Arbitrary restriction of healthcare services — Facility heads can limit or deny services without justification, disproportionately affecting marginalized populations.

amended by deleting subsection (3)"	arbitrary interpretation and application, resulting in the denial or limitation of patients' constitutional right to health.While the provision was intended to ensure patient safety and maintain professional standards, in practice, it has: (a)Granted unchecked legislative power to facility heads, enabling them to unilaterally impose restrictions without clear legal or medical guidelines. (b)Created inconsistent application across facilities, leading to unequal access to healthcare services. (c)Been used, at times, to discriminate against healthcare providers, especially those living with chronic conditions or disabilities. (d)Indirectly denied patients' right to access essential health services by reducing available providers or limiting the scope of services offered.	Workforce demotivation — Healthcare providers subjected to unwarranted conditions face stigma, reduced morale, and potential attrition. Exacerbation of inequities in health access — Patients, particularly in rural and underserved areas, are most affected when qualified providers are restricted. t is recommended that Section 12(3)(a) be deleted in its entirety to safeguard patients' constitutional right to health and prevent arbitrary administrative actions. The deletion will: i. Ensure uniform access to healthcare services nationwide. ii. Protect healthcare providers from unjustified restrictions based on their health status. iii. Promote fair, transparent, and rights-based health governance. Should patient safety considerations require assessment of a healthcare provider's health status, this should be addressed through separate regulations developed by the Ministry of Health in consultation with professional bodies, ensuring due process and adherence to human rights standards.

Recommendation for to amend Section 12 is by inserting a new Section 12A.

One of the key challenges facing healthcare facilities is recovering unpaid hospital bills without infringing on patients' rights. While detaining patients for non-payment has been declared unconstitutional by Kenyan courts, there is currently no clear legal framework providing hospitals with lawful avenues for debt recovery.

The proposed insertion of Section 12A seeks to address this gap by allowing health facilities to request payment guarantees rather than resorting to illegal detention practices.

Amendment to Section 12 of the Principal Act.	1. The principal Act is amended in Section 12 by inserting a new Section 12A as follows –	
	Health facility Payment Guarantee	12A. (1) A health facility may demand a payment guarantee from a patient after medical discharge has been indicated, where there is non-payment in part or in full of hospital bills or medical expenses.
		(2) The payment guarantee under subsection (1) shall be in the form of a promissory note issued to the health facility to facilitate lawful debt recovery.
		(3)A health facility shall ensure that the payment guarantee upholds the patient's rights and dignity.
		(4) The Cabinet Secretary may prescribe in regulations the manner in which payment guarantees to health facilities shall be enforced

Justification for the Proposed Amendment to Introduce Payment Guarantees

The proposed insertion of Section 12A provides a structured and lawful framework through which health facilities may recover unpaid medical bills without infringing on patients' constitutional rights. At present, many hospitals resort to detaining patients as a means of compelling payment, a practice that has repeatedly been declared unconstitutional by Kenyan courts.

This amendment introduces a balanced approach. By allowing health facilities to request a payment guarantee — in the form of a promissory note — after medical discharge is indicated, the law provides hospitals with a legitimate mechanism to facilitate debt recovery while ensuring that patients are not unlawfully detained. It safeguards the dignity of patients as protected under Article 28 of the Constitution by ensuring that financial inability does not result in deprivation of liberty or degrading treatment.

Moreover, the amendment strikes a fair balance between the financial sustainability of healthcare providers and the protection of patient rights. Hospitals require practical solutions to recover costs and remain operational, but these solutions must comply with the Constitution and existing jurisprudence. By formalizing the use of payment guarantees, the proposed Section 12A replaces coercive practices with a rights-based, lawful, and enforceable alternative that benefits both patients and health facilities.

In essence, this amendment promotes a patient-centered approach that respects fundamental freedoms while providing hospitals with a transparent and legally compliant framework for managing unpaid bills. It represents an important step toward harmonizing healthcare financing, constitutional rights, and judicial directives.

Lastly, this provision empowers the Cabinet Secretary responsible for health to develop regulations detailing how payment guarantees will be enforced within the health sector.

REPUBLIC OF KENYA

OFFICE OF THE ATTORNEY-GENERAL
&
DEPARTMENT OF JUSTICE

Our Ref: AG/LDD/119/1/110
Your Ref: NA/DDC/DC-H/2025/87

6th October, 2025

Mr. Samuel Njoroge, CBS
The Clerk of the National Assembly
Clerk's Chambers, Parliament Buildings
P. O. Box 41842-00100
NAIROBI

(1) DDC
&
7/10/25

RE: MEETING WITH THE DEPARTMENTAL COMMITTEE ON HEALTH ON THE CONSIDERATION OF BILLS

Reference is made to your letter under Ref. No. NA/DDC/DC-H/2025/87 and dated 25th September, 2025, requesting for this Office to submit written comments on the Quality Healthcare and Patient Safety Bill, 2025.

We would like to inform you that the Bill was prepared by the Ministry of Health and submitted to this Office for formal drafting as per the established procedure for processing Government Bills. The Bill was drafted in consultation with the Ministry. Therefore, the Bill is in order for consideration by the National Assembly.

We trust this is in order.

Hon. Shadrack J. Mose, CBS
~~SOLICITOR-GENERAL~~

(2) Adan Gindicha, HOD
For the attention of the Dept. Committee on Health.
08/10/25

(3) Mr. Arale
TNA

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(2) Adan Gindicha, HoD
Bring Memo to the attention of the Departmental Committee on Health. DM 6/10/25

(1) DDC & 6/10/25

(3) Mr. Hassan Arale Please deal as instructed 07/10/25

LAW SOCIETY OF KENYA

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NAIROBI

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MEMORANDUM

TO

THE CLERK OF THE NATIONAL ASSEMBLY

ON

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

SEPTEMBER, 2025

Faith Mony Odhiambo, President Law Society of Kenya

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Introduction.

The Law Society of Kenya is a professional statutory body established under the Law Society of Kenya Act, No. 21 of 2014 with a mandatory membership of all Advocates in Kenya.

The organs of the Society are the General Membership, the Council, the Branches and the Secretariat. The Council is the governing body of the Law Society of Kenya. It comprises a President, a Vice- President and eleven other members, all of whom must be members of the Law Society of Kenya. Council members are elected every two years by the members of the Society by means of a secret ballot conducted in accordance with the Law Society of Kenya Act.

Currently, the Council is comprised of The President, The Vice-president and 11 Council members namely:

- President, Faith Mony Odhiambo
- Vice President, Mwaura Kabata
- General Membership Representatives, Tom K'opere, Teresia Wavinya, Hosea Manwa
- Nairobi Representatives, Gloria Kimani, Irene Otto, Stephen Mbugua
- Up-country Representatives, Vincent Githaiga, Lindah Kiome, Hezekiah Aseso, Zulfa Roble
- Coast Representative, Elizabeth Wanjeri
- Secretary/CEO, Florence W. Muturi

One of the Law Society of Kenya statutory objects as provided in section 4(a) of the Act is to assist the Government and the courts in all matters affecting legislation and the administration and practice of law in Kenya. Pursuant to this statutory mandate, the Law Society of Kenya makes a presentation on the **Quality Healthcare and Patient Safety Bill, 2025.**

GENERAL COMMENTS.

The Quality Healthcare and Patient Safety Bill, 2025 seeks to give effect to Article 43(1)(a) of the Constitution; to provide for the responsibility of the National and County governments in the realisation of quality of healthcare for patients, to provide for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, registration, licensing and accreditation of health facilities, to set and provide for implementation of standards for quality of healthcare and for connected purposes.

The Bill first came to the attention of members of the Law Society of Kenya (LSK) through an invitation to the LSK from the Ministry of Health to attend a Stakeholder Engagement Forum on the Bill. Subsequently, members of the LSK Medico-Legal Committee who attended the Forum on 19th June 2025 at Weston Hotel, Nairobi, prepared and submitted a Report to LSK, noting several concerns pertaining to the Bill.

At the time the Forum took place, the Bill had yet to be submitted to the National Assembly and was still a legislative proposal. In our Report, we stated that it was premature for LSK members to comment, hoping the Forum's discussions would prompt the Ministry of Health to consult healthcare stakeholders and make necessary amendments before sending the Bill to the National Assembly.

We acknowledge that the Ministry of Health indeed, took into consideration some of the concerns raised at the Forum (including by the LSK) and made the following amendments to the Bill:

i) The Bill submitted to the National Assembly spared the HIV and AIDS Tribunal which was previously slated for disestablishment. The Dispute Resolution Tribunal established under the Social Health Insurance Act is however still to be done away with (see **Clause 83** of the Bill) and be succeeded by a proposed Health Care Tribunal; and

ii) The Bill now gives the Director-General for Health the power to develop and publish clinical guidelines, rather than the Cabinet Secretary. However, this would neither cure the objections previously raised by healthcare stakeholders

in the Forum concerning misplaced expertise nor cure potential conflicts of interest on the part of the Director-General.

Still, some clauses in the Bill make reference to the Cabinet Secretary prescribing scopes of practice (e.g. **Clause 18(1)(c)**. This was one of the objections to the Bill that was raised by attendees at the Forum and articulated in our Report.

We have reviewed the published Bill and note that while some earlier concerns were addressed, several provisions remain problematic. Below are our specific comments and justifications on selected clauses.

SPECIFICS COMMENTS.

No	Section	Provision/Issue	Proposal	Justification
1.	Clause 2	*"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. The clause fails to capture the urgency of an emergency in its description, and further,	1. The definition of *"Emergency treatment"* in the Health Act (CAP 241) (as amended) can be retained (and the Health Act referred to in the definition). The word 'medical' in '*Emergency **medical** treatment*' can be done away with as it is superfluous. The definition would therefore read as follows: "Emergency **medical** treatment" has the same	It prevents ambiguity and incorporates the urgency and immediacy of emergency care, which is a defining element of emergencies.

		is drafted in a way that is quite vague and lacking in clarity.	meaning assigned to it under Section 2 of the Health Act. **<u>Alternatively:</u>** 2. The definition of *"Emergency treatment"* that is used in the Health Act (CAP 241) can be expanded, if the sponsor of the bill specifically intends to include in the definition the <u>transportation</u> of patients who require emergency care. In this case, the proposed definition can read as follows: "Emergency treatment" *refers to necessary immediate healthcare that must be administered to prevent death or worsening of a medical situation,* ***and includes healthcare services administered to patients***	

			while in transit to or from a health facility.	
2.	Clause 2	The definition of "healthcare services" in the Health Act, although broad, could benefit from a slight but significant change (see next column) that would make it more comprehensive. Since the definition of "healthcare services" in the Health Act is also shared by this Bill, this change to the Health Act is recommended.	We propose as follows; - In the Health Act, 'healthcare <u>professionals'</u> is used instead of 'healthcare <u>providers'</u>, yet the definition of 'healthcare **provider'** includes a health professional. The better phrase to be used in the definition (as it is all-encompassing), is therefore 'healthcare **providers.** The proposed definition should read as follows: "Healthcare services" means the prevention, promotion, management or alleviation of disease, illness, injury, and other physical and mental impairments in individuals, delivered by healthcare professionals' **<u>providers</u>** through the healthcare system's routine health services,	It ensures the definition of *"healthcare services"* fully captures the broad spectrum of healthcare delivery.

			or its emergency health services."	
3.	Clause 2	"Quality of healthcare" 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; The phrase being defined is not very clear. The 'Quality **of** healthcare' can be good, bad, mediocre, or have other descriptors. "**Quality healthcare**", on the other hand, connotes positive attributes, which may be	The defined term should be **'quality healthcare'.** The word '*of*' in 'quality of healthcare' should therefore be deleted where appropriate (since there are instances in the Bill where 'of' may be correctly used). The definition should therefore read as follows: **"Quality ~~of~~ healthcare"** 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;	It prevents ambiguity.

		what the defined term should be referring to.		
4.	Clause 3	The objects of this Act are to – (a) Guarantee patient rights and patient safety; One should hesitate to use the word "guarantee" in legislation when it comes to patient rights and safety, but rather, take a more realistic approach that speaks to efforts to ensure that patient rights and safety are emphasised. This is because (as has been acknowledged in the Bill), adverse events can happen in the course of treatment. What then happens to the 'guarantee' of safety that had been promised in the Bill on the	**Clause 3(a)** could be re-worded as follows: a) ***Implement measures that safeguard*** patient rights and patient safety;	Laws generally require reasonable measures and standards rather than absolute guarantees, particularly in areas involving risk and human error.

		occurrence of an adverse event? The patient's safety will already have been breached (thereby nullifying the guarantee), and the only recourse might be some form of compensation or damages.		
5.	Clause 5 (a)	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. The main issue in this sub-clause is the absence of a requirement for the Cabinet Secretary to act	Clause 5(a) should be re-worded as follows: The Cabinet Secretary shall- a) ***In consultation with healthcare regulatory bodies or relevant healthcare bodies or agencies*** develop and ensure implementation of policies, standards, guidelines and protocols that ensure the provision of quality healthcare services including staffing norms and standards".	It ensures that policies, standards and guidelines are informed by the knowledge and experience of regulatory bodies and other relevant stakeholders.

		in consultation with other bodies or persons when developing and ensuring standards, protocols, etc. This lack of participation and consultation with relevant healthcare bodies is inadvisable, given the expertise present in, say, regulatory bodies, and further, the clause as drafted deprives itself of the benefit of enrichment through the views of different stakeholders.		
6.	Clause 5 (c)	Clause 5(c) "Ensure continuous improvement in the outcomes that are achieved from the provision of the healthcare services, **including –** .... **(iv):**	It is paramount to clarify what '***experience***' means in this context since the two senses of 'experience' that are described would call for different measures to gauge *continuous improvement*. The first sense would call for enhanced training and knowledge to be given	It prevents ambiguity.

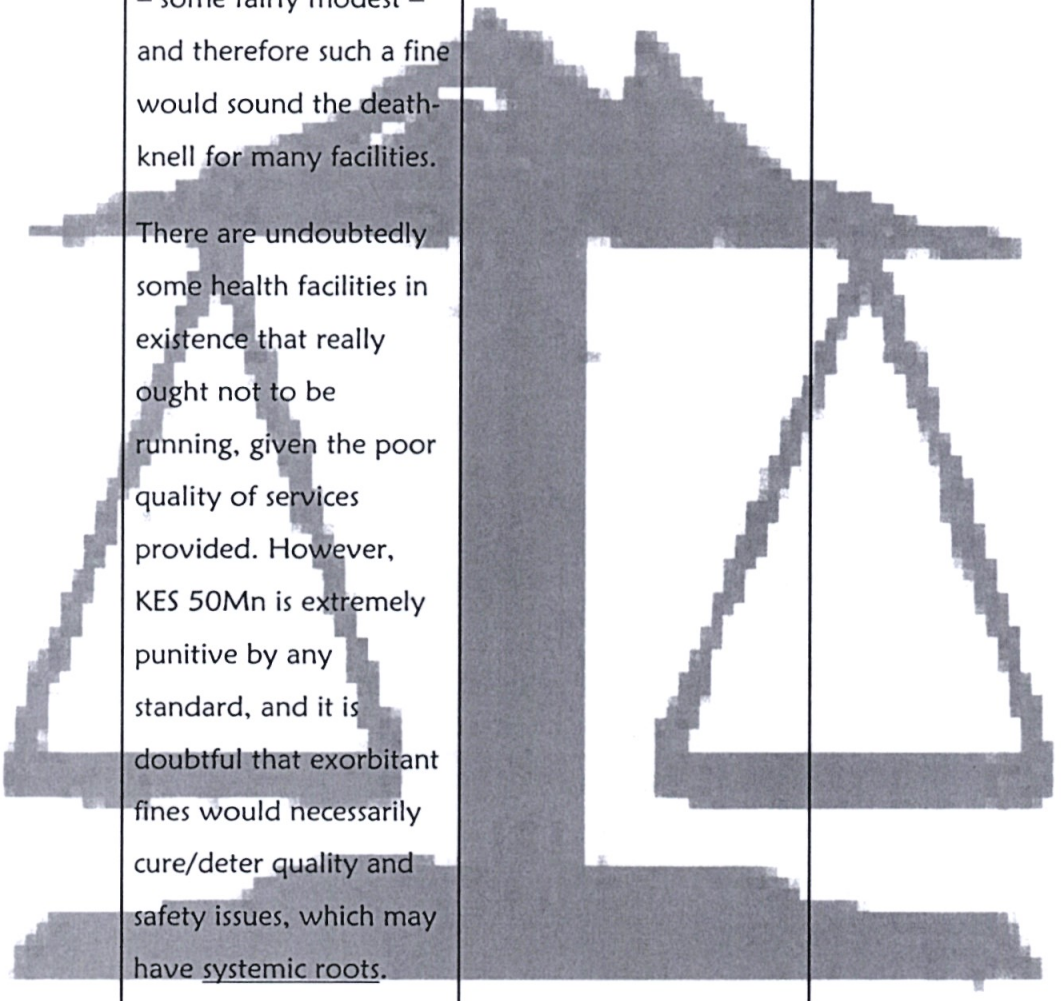
		"the healthcare provider's experience. It is not clear what '*experience*' means here – Is it 'experience' in terms of the length of time and expertise that a healthcare provider has, or is it '*experience*' in the sense of their day-to-day feelings/observations pertaining to their work?	to healthcare providers, while the second would require improvement in the terms of employment and the working environment of healthcare providers.	
7.	Clause 6 (e)	Clause 6 (e) assigns county governments the responsibility of monitoring the quality of healthcare in private and faith-based health facilities which is the responsibility of the Quality Health Care and Patient Safety Authority as assigned under clause 27 (f).	Amend Clause 6 (e) by inserting the word "county" after the words "healthcare in all" and by deleting the words "private and faith-based health facilities".	The responsibility of monitoring the quality of healthcare in private and public facilities should be left to the Authority as assigned under clause 27 (f). Assigning this responsibility to the counties creates conflict of interest since the county government are also providers of similar health services. In addition, it will amount to duplication of regulatory mandate and

				roles because both the county governments and the Authority will be seeking to monitor the same facilities, which will negatively affect business of the private sector and faith-based facilities.
8.	Clause 10	"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 about their health". The use of the word 'Notwithstanding' in Clause 10(a) of the Bill is not the most appropriate, given that it appears to water down Section 8 of the Health Act, which contains important provisions.	We propose that the clause be amended to read as follows: "**Further to** 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 about their health".	***"Further to"*** clarifies that the Bill complements Section 8 rather than overrides it.

9.	Clause 11(1)(c)	"Every person has the right to access quality healthcare services that are – ... b) Compliant with quality of healthcare standards prescribed under this Act". The proposal regarding the phrase "Quality of healthcare" articulated above should also apply to Clause 11(c) – the applicable phrase should be "quality healthcare" and not "quality of healthcare". This amendment should also be made to all clauses in the Bill where this change is applicable) – e.g. Clauses 17(1), 17(3), 18(1)(a), and several others.	Clause 11(1)(c) should read as follows: "Every person has the right to access quality healthcare services that are – ..... c) Compliant with **quality ~~of~~ healthcare** standards prescribed under this Act".	It ensures that there is consistency in the use of terminology.
10.	Clause 18 (1 & 2)	18(1) A health facility shall—	Clause 18(1) (c) can be amended as follows:	It is inappropriate for the Cabinet Secretary to prescribe scopes of practice,

		a) Adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as prescribed by the Cabinet Secretary; Clause 18(1)(c) is problematic as it fails to acknowledge the critical role of healthcare regulators, when it comes to scopes of practice. The Cabinet Secretary ought not to prescribe scopes of practice, but simply provide oversight to the relevant regulatory bodies. There are two main issues with Clause 18(2): i)The outsized fine for a non-compliant health facility raises questions as to whether the actual	18(1) 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 relevant healthcare regulatory bodies;** **<u>Alternatively:</u>** c) Adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as prescribed by the Cabinet Secretary **following the recommendation of the relevant healthcare regulatory bodies;** --- ---	as this is the exclusive mandate of the respective professional regulatory bodies established under statute.

		intention in the Bill is to grind such facilities to a halt. The Bill does not seem to have taken into account that health facilities come in all sizes – some fairly modest – and therefore such a fine would sound the death-knell for many facilities. There are undoubtedly some health facilities in existence that really ought not to be running, given the poor quality of services provided. However, KES 50Mn is extremely punitive by any standard, and it is doubtful that exorbitant fines would necessarily cure/deter quality and safety issues, which may have systemic roots. ii)The reference to a jail term/imprisonment for a health facility is peculiar and cannot be implemented. The Bill		



		must correctly locate and specify **the person** who should be held responsible for the failures of quality care and patient safety. Again, such failures *may* be due to systemic issues outside the control of health facilities, and the sponsor of the Bill ought to bear this in mind.		
11.	Clause 20 (2)	The Director-General shall develop and publish clinical guidelines from time to time.	Clause 20(2) could be improved by expressly permitting the Director-General to consult with other persons/bodies in the making of guidelines.	It ensures that the guidelines are informed by the knowledge and experience of other persons/ bodies and other relevant stakeholders.
12.	Clause 21 (2)	Every health facility shall audit the safety of the health facility and submit an annual safety report to the Authority, setting out measures to improve the health facility. Several concerns arise with Clause 21(2):	In view of all the concerns above, the most ethical route is for the Bill to provide for either: **a)** the envisaged Quality Healthcare and Patient Safety Authority ("the Authority") to undertake this role --; or,	To preserve the integrity of audits, the most ethical and effective approach is to vest responsibility either in the Authority or in independent auditor. This will ensure impartiality, accountability and fairness.

		i)Is the health facility expected to audit its own safety through an internal audit? ii)What assures the independence or impartiality of an audit emanating from the health facility itself? iii)Why are there no provisions for an *independent entity* to audit the health facility? iv)A requirement for an independent audit would certainly have financial implications for the health facility. Who/what would the most suitable party to absorb this cost? v)Given the varying sizes/types of health facilities, some may need to pay more funds to be audited than others. How can the Bill put in place measures to ensure that there are no	**b)** require health facilities to pick an independent auditor from a pre-approved/prequalified list (these measures, however, may also have their cons – including the possibility of a health facility compromising any such entities). In the event the Authority is to carry out the Audit, funds should be budgeted for this task by national government.	

		corrupt dealings that would influence the making of a favourable report when the situation on the ground calls for sanctions including closure of the health facility?		
13.	Clause 22 (1)	Lack of a requirement for the Cabinet Secretary to act ***in consultation with*** other bodies or persons.	We propose as follows: "The Cabinet Secretary, **in consultation with relevant healthcare and patient safety bodies,** shall develop a quality improvement framework for health facilities, which shall …	It ensures that the framework is informed by the knowledge and experience of other persons/ bodies and other relevant stakeholders.
14.	Clause 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 health services.	We propose that since omissions cannot strictly be 'committed', the word 'committed' should be deleted from this subsection.	Deleting the word committed eliminates potential interpretive confusion, enhances clarity and ensures the clause accurately reflects the legal intent to cover all forms of liability arising from acts or omissions in the course of providing health services.

	Clause 27 (o)	The functions of the Authority shall be to – ... o) perform such other functions as may be as necessary for the promotion of the objects of this Act or prescribed under any other written law. There is some repetition of the word 'as',	We propose the deletion of as that is between the words be and necessary. o) perform such other functions as may be **~~as~~** necessary for the promotion of the objects of this Act or prescribed under any other written law".	This amendment enhances readability and ensures consistency with standard drafting practice.
15.	Clause 29	This clause concerns the composition of the Board of Directors of the Authority. Clause 29 as drafted is overwhelmingly populated by appointees of the National Government's Executive arm. The Cabinet Secretary is given undue latitude to appoint persons to the Board without the involvement of healthcare stakeholders,	The composition of the Board of Directors of the Authority in Clause 29 should be reconsidered, so as to include a diversity of appointees, recommended by healthcare stakeholders who are outside of the National Government's Executive arm. Healthcare professional bodies, healthcare stakeholders, and patient safety representatives	Private and faith-based healthcare service providers play a critical role in health care service delivery in Kenya; therefore, they should be represented in the Board of the Authority. The person representing the public should have knowledge and experience in healthcare management or quality improvement. This will ensure there is value addition to the representation in the Board.

		who are better placed to recommend their own representatives to the Board. This clause is exclusionary, and increases the perception (rightly so), of the Board being a preserve of political appointees. Further, the clause as drafted fails to give space to other healthcare professional bodies and healthcare stakeholders, as well as patient representatives, who have expertise and broad perspectives that would enrich the Board. **Clause 29 (g)** provides generally for representation of health care providers, which includes individuals or organizations. The clause does not provide for representation of private and faith-based healthcare providers,	must be included in the Board of Directors. Amend Clause 29 (g) by inserting the words "private and faith- based" after the words "to represent" and by inserting the words "nominated by the forum of private and faith-based healthcare providers"	

		who are leading service providers in the country Clause 29 (g) provides for appointment of a person to represent the public. This leaves room for the Cabinet Secretary to appoint any person irrespective of their expertise on health-related matters.		
16.	Clause 30 (1)	This clause concerns the qualifications and experience of the Chairperson of the Board of Directors of the Authority. Clause 30(1), by pegging the educational level of the Chairperson of the Board of Directors of the Authority to a Bachelor's degree, is setting the bar rather low. Given that the Board will be required to set standards for other healthcare professionals to follow	Clause 30(1) must **raise the bar** regarding the educational qualifications of the Chairperson of the Board of Directors of the Authority, by at the very least, requiring a ***minimum*** of **a Master's degree** in a relevant area (in addition to the other requirements listed).	Pegging the minimum educational qualification of the Chairperson at a Bachelor's degree risks undermining the credibility and effectiveness of the Authority's governance framework. This higher standard strengthens the Authority's legitimacy, enhances stakeholder confidence, and aligns the leadership of the Board with the level of responsibility it carries in shaping national healthcare standards and safeguarding public health.

		(many trained to high levels), it surely should require a Chairperson with credible post-graduate qualifications of <u>at least a</u> <u>Master's level, in addition to the years of working experience required.</u>		
17.	Clause 40 (2)	**Clause 40(2):** "Despite subsection (1), nothing in this section shall exempt a member of the Board, officer, employee or agent of the Authority from individual responsibility for unlawful or criminal act committed by the member of the Board, officer, employee or agent of the Authority." This is more a typographical rather than substantive error – to add the letter '*s*' to the word 'act', so that it is in plural form.	"Despite subsection (1), nothing in this section shall exempt a member of the Board, officer, employee or agent of the Authority from individual responsibility for unlawful or criminal act<u>s</u> committed by the member of the Board, officer, employee or agent of the Authority."	Retaining the singular "act" could be misinterpreted to mean that liability only attaches to one unlawful or criminal act, leaving a loophole where multiple unlawful or criminal acts might not be captured. Changing it to "acts" ensures comprehensive coverage and closes any potential interpretive gap.

18.	Clause 42	(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" ---------- **(6) "The Cabinet Secretary shall develop standards for the construction, operation and decommissioning of a health facility."**	Proposed amendment: "The Cabinet Secretary shall **in consultation with relevant experts and healthcare bodies,** prescribe the requirements for – a) health facilities; b) ambulances; c) **aircraft designated for use in medical evacuation and transport**; d) medical camps; and e) such other health facility as may be prescribed by the Cabinet Secretary." ---------- - Proposed amendment:	It ensures that policies, standards and guidelines are informed by the knowledge and experience of regulatory bodies and other relevant stakeholders.

			(6) "The Cabinet Secretary shall **in consultation with relevant experts and healthcare bodies** develop standards for the construction, operation and decommissioning of a health facility."	
19.	Clause 46 (2&3)	Clause 42(2) concerns a *non-mandatory* (i.e. **optional**) notification by the Authority to a health facility whose registration it intends to suspend, while Clause 43(3) concerns the health facility's right of appeal to a Tribunal upon receipt of such notice from the Authority. The provisions and timelines set out in Clause 46(2) and 46(3) do not give a health facility **sufficient notice or opportunity to** challenge/appeal a decision by the	1) Clause 46(2) must make it **mandatory** for the Authority to communicate a decision to suspend the registration of a facility, so as to give the facility sufficient **opportunity** to appeal if it so wishes. Clause 46(3) must clarify its **timelines** to give a health facility sufficient **time** to lodge an appeal if it so wishes. Therefore, the clock for a facility facing the threat of	Our proposal aligns with Article 47 of the Constitution and Sections 3&4 of the Fair Administrative Action Act, 2015, which require adequate notice, reasons for decisions and an adequate opportunity to challenge adverse decisions. The current drafting risks violating these standards and exposing the Authority's decisions to judicial review for procedural unfairness.

		Authority to suspend a certificate of registration. 1) In Clause 46(2), the Authority "**may,** *at least twenty-one days before the date of the intended suspension, notify the health facility of such intention…and shall require the health facility to furnish reasons why the health facility should not be suspended, within fourteen days of service of the notice.*"	suspension should only start ticking from **the date of service of the notification from the Authority,** and not "*from the day of the notification under subsection (2)*" – this is confusing, unclear, and is bound to be a litigation question in future if not amended.	
		2) In Clause 46(3), a person affected by the decision of the Authority "*may, **within twenty-one days***		

		from the day of the notification under subsection (2), lodge an appeal *before the Tribunal.* The questions arising therefrom are: i) If the Authority may (in Clause 46(2), notify a person/health facility (an optional act), how then can an affected person lodge an appeal in the event they are not notified by the Authority? The affected person cannot appeal that which they know not about. ii) If the Authority may (in Clause 46(3), notify a person "twenty-one days before the date of the intended suspension", yet the affected person is also to		

		lodge an appeal "within twenty-one days from the day of the notification under subsection (2)", it is surely clear that for the affected person/health facility, their twenty-one days run out just as soon as/on the day the intended suspension kicks in. There is therefore, in reality, no twenty-one-day period for the affected party to lodge an appeal, but a much shorter time – if at all – since they may not even have been notified of the intention to suspend in the first place. If the intention of Clause 46(3) is for the twenty-on day period to run from the date of service of the notice (rather than "from the date of the notification" as it currently states), it		

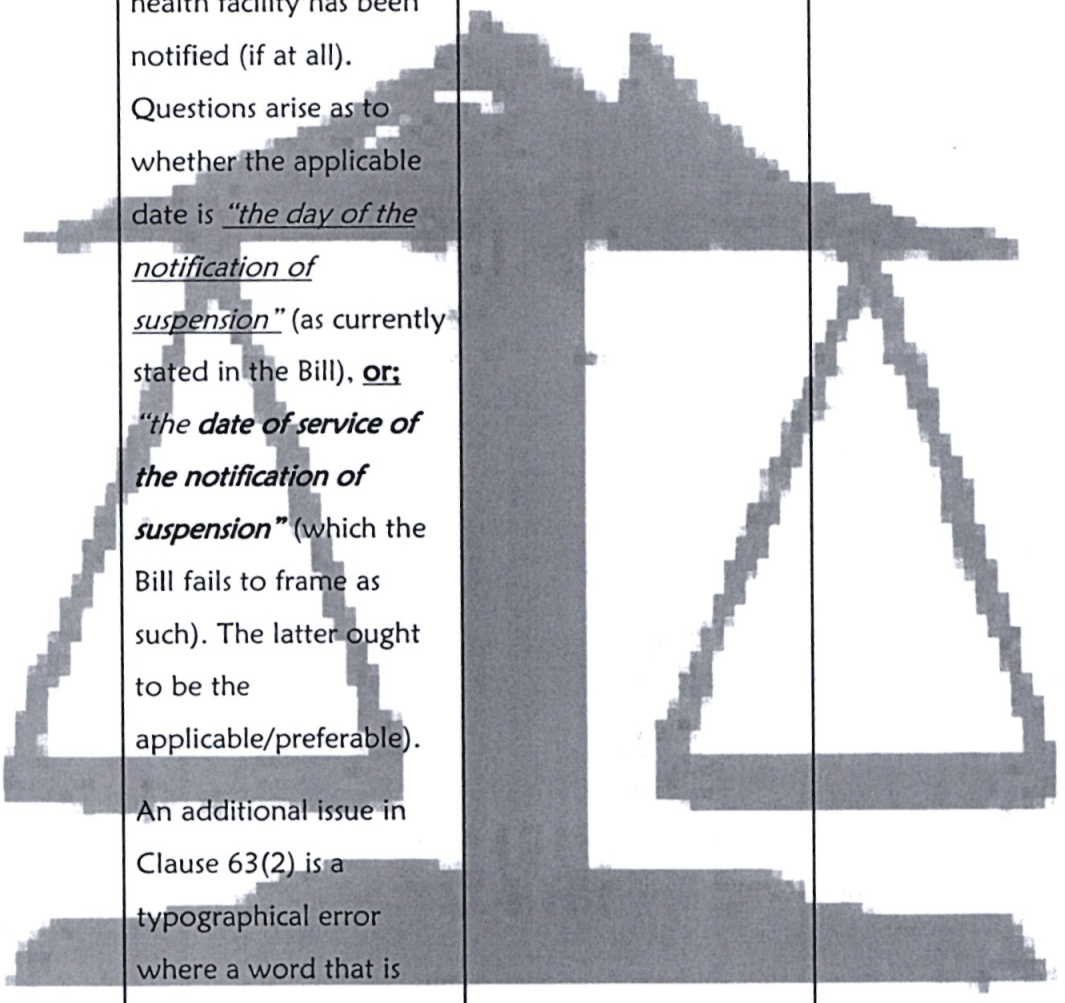
		should make this clear by appropriate re-drafting of the subsections.		
20.	Clause 47	Clause 47(2) concerns a *non-mandatory* (i.e. **optional**) notification by the Authority to a health facility whose registration it intends to revoke, while Clause 47(3) concerns the health facility's right of appeal to a Tribunal upon receipt of such notice from the Authority. An additional issue in Clause 47(3) concerns the use of the word "licence" (rather than **"certificate of registration"** in Clause 47(3), which appears to be an error.	We propose that the provision be made mandatory by replacing the word ***'may'*** with ***'shall.'*** Further, we propose the word ***'licence'*** should be deleted and replaced with ***'certificate of registration'*** for consistency.	Our proposal aligns with Article 47 of the Constitution and Sections 3&4 of the Fair Administrative Action Act, 2015, which require adequate notice, reasons for decisions and an adequate opportunity to challenge adverse decisions. The current drafting risks violating these standards and exposing the Authority's decisions to judicial review for procedural unfairness. Correcting the error ensures consistency, legal certainty, and prevents interpretive confusion.

21.	Clause 54 (2 & 4)	Clause 54(2) concerns a *non-mandatory* (i.e. **optional**) notification by the Authority to a health facility whose licence it intends to suspend, while Clause 54(4) concerns the health facility's right of appeal to a Tribunal upon receipt of such notice from the Authority.	The amendments proposed for Clause 46(2) and (3); and Clause 47(2) and (3) above, also apply to Clauses 54(2) and (4). Further the erroneous reference in Clause 54(4) to "*notification under subsection (1)*", should be corrected to read "*notification under* **subsection (2)".**	Justification similar to that provided under Clauses 46(2 & 3) and 47 (2& 3).
22.	Clause 55 (4)	Clause 55(4) concerns the discretion of the Authority to revoke a licence after receiving reasons from a health facility. The issue of timelines arises in Clause 55(4), where "*the Authority shall, after considering the reasons, decide on whether or not to revoke the licence*".	Clause 55(4) should include an obligation on the Authority to render its decision concerning revocation *within a given time-frame* – **Fourteen, or Twenty-One Days,** seems to be a reasonable time for a facility to receive a written decision from the Authority.	Setting a specific timeline provides certainty. It strikes a balance between allowing the Authority sufficient time to fairly consider the reasons advanced by the facility and ensuring that the facility receives a timely written decision.

23.	Clause 63(2) & (4)	(2) "Where the Authority intends to suspend, he [sic] 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 accreditations should not be suspended, within fourteen days of service of the notice." The provisions and timelines set out in Clause 63(2) and 63(4) do not give a health facility **sufficient notice or opportunity to** challenge/appeal a decision by the Authority to suspend its accreditation – firstly, because it is couched as *non-mandatory* (i.e.	The amendments proposed for Clauses 46(2) & (3); 47(2) & (3); and 54(2) & (4), also apply to Clauses 63(2) and (4). The applicable date from which any time should begin to run (where a health facility is facing suspension of accreditation), should be from ***the date of service of the notification of suspension.*** The typographical error in Clause 63(2) where "*the*", (between 'suspend' and 'accreditation'), has been typed as "**he**", should also be corrected.	Justification similar to that provided under Clauses 46(2 & 3), 47 (2& 3) & 54 (2&4).

		optional) for the Authority to notify a facility, and secondly, because the timelines given overlap/expire before a health facility has any meaningful opportunity to respond. The same issues pointed out above concerning **Clauses 46(2) & (3); 47(2) & (3); and 54(2) & (4)** are replicated here, but with one difference – Clause 63(4) clarifies that the notification at issue is the "notification of suspension", and not just a general "notification". This clarification cannot be assumed to apply to previous sections pointed out here. **<u>However</u>**, that addition still does not give a health facility sufficient		

		notice (time-wise) to respond, since, as pointed out earlier, the time given to a health facility for response may run out even before a health facility has been notified (if at all). Questions arise as to whether the applicable date is *"the day of the notification of suspension"* (as currently stated in the Bill), **or;** *"the* ***date of service of the notification of suspension"*** (which the Bill fails to frame as such). The latter ought to be the applicable/preferable). An additional issue in Clause 63(2) is a typographical error where a word that is supposed to be "*the*", (between 'suspend' and 'accreditation'), has been typed as "**he**".		



		(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."		
24.	Clause 57 to 64	Clause 57 to 64 provides for accreditation of health facilities by the Quality Health Care and Patient Safety Authority, which is conflict of mandates and roles because the Authority's mandate is to regulate the healthcare facilities and not accredit the facilities. In addition, the clauses usurp the function and mandate of the Kenya Accreditation Service (KENAS), which is the government body responsible for	Amend Clause 57 to 64 by deleting the word "Authority" and substituting therefor the words "Kenya Accreditation Service", save for any section that may specifically be referring to the reasonability of the Authority to issue licenses under the Bill.	Licensing of healthcare facilities should be separated from accreditation. The conventional practice is that the function of accreditation is carried out by an independent body from the one issuing licenses. The Authority should focus on licensing and regulating the healthcare facilities. The Kenya Accreditation Service (KENAS), is the government body responsible for accreditation services for standards and quality management. By separating the licensing and accreditation roles and

		accreditation services for standards and quality management.		having them being carried out by different bodies, the Bill will enhance accountability and improvement of quality services.
25.	Clause 75	The Authority shall, by Gazette Notice, appoint duly qualified persons, to be inspectors of the Authority for the purposes of this Act. The phrase "duly qualified" is rather vague and non-specific.	It is recommended that the Regulations under this Act sets out at the very least, the minimum qualifications and experience expected of an inspector of the Authority.	Such a requirement will aid in enhancing the Authority's transparency, as well as ensuring a high level of accountability for the inspectors.
26.	Clause 83	This clause generally concerns the proposed 'Healthcare Tribunal' – "the Tribunal". It is inadvisable to mix the functions and mandate of the Dispute Resolution Tribunal under the Social Health Insurance Act, 2023, with what is clearly a mandate (Quality Health and Patient	The proposal in **Clause 83(2)** to subsume what should have been a separate Dispute Resolution Tribunal into the proposed Healthcare Tribunal, is likely to leave persons affected by disputes arising from social health insurance without specialist expertise and	Merging the functions of the proposed Healthcare Tribunal with the Dispute Resolution Tribunal established under the Social Health Insurance Act, 2023, risks undermining the effectiveness and efficiency of both bodies.

		Safety), that requires a different set of knowledge, skills, and approach. The expertise required to fulfill the mandate of the Bill is vastly different from potential disputes that could arise under the Social Health Insurance Act, which disputes are likely to concern matters such as levels of insurance coverage, refusals to approve treatment, etc.	determinations of their complaints. Further, complaints arising from the Social Health Insurance Act, 2023, may be numerous, and therefore, dominate other types of matters brought before the Healthcare Tribunal at the expense of complaints that touch on quality healthcare and patient safety. Clause 83(2) should be carefully reconsidered, and the final Bill must reflect a decision that best serves *wananchi* without their having to suffer undue delays, as well as one that bears in mind the need for prudent use of the nation's already-strained finances.	
27.	Clause 83(6)	The quorum for a meeting of the Tribunal shall be three members.	Amend Clause 83(6) to provide that one member shall be an	Given that the Tribunal exercises quasi-judicial functions, requiring that at

			Advocate of the High Court of Kenya.	least one member of the Tribunal be an Advocate of the High Court of Kenya, it ensures that the Tribunal's deliberations and decisions benefit from legal expertise, particularly in the interpretation and application of the law.
28.	Clause 84	This clause generally concerns the jurisdiction of the Tribunal). Clause 84 as drafted is excessively broad in scope and ambition, and the jurisdiction granted to the Tribunal disregards the nature of disputes that require specialist and professional knowledge and expertise, wrongly presuming that they are capable of resolution by the Health Tribunal. Clause 84(3) is a case in point:	Clause 84 must confine the Tribunal to **quality healthcare and patient safety disputes that broadly involve healthcare facilities,** and not exceed its *anticipated role and* powers to veer into the territory of healthcare regulatory bodies and the professionals they oversee (including that of the Kenya Health Professions Oversight Authority). Even where a healthcare professional is implicated in an unlawful act, and the Authority's inspector say, temporarily suspends	The Clause as currently drafted grants the Tribunal an excessively broad jurisdiction that overlaps with the mandates of healthcare regulatory bodies, thereby undermining their statutory roles and professional expertise. The Tribunal's jurisdiction should be confined to disputes on quality healthcare and patient safety within health facilities, leaving professional regulation to the respective regulators. Further, to safeguard efficiency and justice, the Tribunal should be required to hear and determine matters within ninety days of filing and

		"*The Tribunal shall have original jurisdiction on* ***any dispute*** *between health facilities, patients, healthcare providers and regulatory bodies.*" Such an excessively wide jurisdiction is bound to cast aside the role of **healthcare regulatory bodies** in providing oversight, and disciplinary measures, over their professionals. The **composition** proposed of the Healthcare Tribunal as set out in Clause 83 **cannot,** even with the best of intentions, match or supersede the expertise found in healthcare regulatory bodies, which have clearly-defined statutory roles. A single Tribunal is not capable of resolving such a wide array of potential disputes, with	the operations of a health facility under Clause 79, the inspector should be at liberty to refer the healthcare professional to his/her relevant regulatory body for disciplinary action under Clause 79(1)(b). --- Proposed amendments to Clause 84(6)(a) and an **additional 84(6)(b)**: **Clause 84(6):** a) "The Tribunal shall hear and determine matters referred to it expeditiously, and shall endeavour to do so **within ninety days of the filing of the matter.**" b) Where a matter remains undetermined after ninety days, the Tribunal shall furnish the parties with written reasons for the delay, and a time-frame within	where delays occur, furnish written reasons and a clear time-frame for determination. This ensures accountability, timeliness, and alignment with constitutional principles of good governance.

		such a diverse array of players --healthcare facilities, providers, patients, etc. --, and numerous health professional cadres, as is being granted by its jurisdiction. --- There ought to be a requirement that the Tribunal hear and determine matters within a **specific time-frame** from the date the matter is filed with the Tribunal.	which the matter shall be determined.	
29.	Clause 93 (2) (i)	It provides for to prescribe for ambulances services. However, this is a narrow approach as it only focuses on ambulances, which are part of the wider pre-hospital care or emergency medical services.	Amend Clause 93 (2) (i)) by deleting the word "ambulances services" and substituting therefor the words "emergency medical services or pre-hospital care"	The appropriate terms are emergency medical services or pre-hospital care, which are more comprehensive, inclusive and covers with wider spectrum of the services, including ambulance services.
30.	First Schedule	Unless an unanimous decision is reached, a	Amend Clause 1(8) by replacing the word **"an"**	The current wording is a typographical error that

	Conduct of Business and Affairs of the Board: Clause 1(8)	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". The word '*an*' is a typographical error, and should be replaced with '**a**'.	with **"a"** so that it reads: "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."	should be corrected to ensure grammatical accuracy, clarity, and consistency with standard legislative drafting practice.
31.	Second Schedule: Consequential Amendments to Other Acts:	a)The re-definition of "healthcare provider" is problematic, unnecessary, and is inferior to the existing definition in the Health Act for the following reason;- The proposed definition of '*healthcare provider*' in the Bill does not distinguish between persons currently **regulated by a healthcare professionals' regulatory body** (e.g. KMPDC, Nursing Council of Kenya, etc.)., and persons currently not regulated, or at best, are only	The existing definition of 'healthcare provider' and "health facility" as defined in the Health Act should be **retained.** Although the current definition of 'health facility' in the Health Act suffices, elements such as morgues, may be incorporated.	The proposed re-definitions are unnecessary and risk creating confusion.

		peripherally regulated (e.g. herbal medicine practitioners). b) The proposed re-definition of "*healthcare services*", it states that healthcare services are *"delivered by healthcare professionals"*. If this is the case, why then not let the Health Act's prevailing/existing definition of "healthcare providers" stand? i)The Bill employs he word "healthcare professional" in the definition of healthcare services, but ignores **Point (i) (b)** above – that in Kenya, currently, not all persons providing healthcare services are regulated, and so not all 'healthcare providers' are health professionals. In other words, a **'healthcare professional'**		

		IS a healthcare provider, but not all 'healthcare providers' are healthcare professionals. --- c)The re-definition of 'health facility' manages to miss out important elements that are currently in the Health Act, even as it expands the definition of a 'health facility'. For instance, going by the proposed (new) definition in the Bill, is a **doctor's consulting room** a health facility? If so, the removal of the word 'out-patient' from the new definition (while it exists in the current definition in the Health Act), is an anomaly that ought to be rectified. Further omissions in the proposed definition that are key, include leaving out the phrase "*the*		

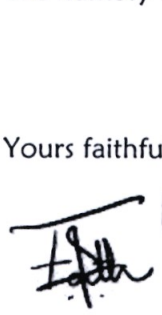
		whole or part of a public or private institution, building or place", Describing a 'health facility' **primarily** as "an institution" (in the Bill), is also limiting its scope. --- **Generally:** All other 'Consequential Amendments to other Acts' listed in the Second Schedule of the Bill must be re-checked, re-drafted and/or deleted where their effect is to propose the extension of the Authority's or Tribunal's powers into what should be the remit of **healthcare regulatory bodies, and in particular, scopes of work, oversight, and discipline of healthcare professionals.**		

CONCLUSION

It is important to note that for the Bill to meet its objectives, it requires adequate resources in terms of human, infrastructural, financial and capacity-building among others. If the Bill is enacted, the National and County Governments must be prepared to commit sufficient resources to see to it that the Bill's aims are not frustrated.

We humbly submit that our comments be considered before enactment of the Bill.

Yours faithfully,



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MEMORANDUM BY CLINICAL OFFICERS COUNCIL ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

Preamble

The Clinical Officers Council of Kenya is a state corporation, established under Act of parliament No. 20 of 2017 Laws of Kenya, with a mandate to regulate training, registration and licensing of all Clinical Officers in Kenya.

The WHO defines quality health services as those that are effective, safe, people-centered, timely, equitable, integrated, and efficient. These characteristics are often assessed using quality indicators, which are standardized, evidence-based measures that help monitor and track healthcare performance and outcomes. These include;

- **Effectiveness: -** Providing services based on scientific knowledge to all who could benefit e.g. maternal health indicators (rates of severe maternal morbidity and mortality). Lack of diagnostics, equipment and other essential utilities serve as hindrances to this.
- **Safety: -** Avoiding harm to patients from the care provided e.g hospital-acquired infections, adverse drug events among others. Lack of adequate Personal Protective Gear continues to impact safety negatively.
- **People-centeredness: -** Providing care that respects individual patient preferences, needs, and values e.g patient satisfaction with care, Involvement of patients in treatment decisions and Availability of patient education and support. Staff shortages continue to lower Patient Satisfaction due to long waiting times and burnout among clinicians.
- **Timeliness: -** Reducing waits and delays for both patients and providers e.g. Time to treatment initiation and Availability of services outside of regular business hours among others. Negatively affected by staff shortages, poor digital infrastructure among others.
- **Equity: -** Providing care that does not vary in quality due to factors like location or socioeconomic status e.g disparities in access to care based on location and Disparities in outcomes based on socioeconomic status among others. Disparities in access to care still exist especially in rural and hardship areas where specialists are few and often overwhelmed.
- **Efficiency: -** Avoiding waste of resources e.g appropriate use of resources

- **Integration: -** Providing coordinated and continuous care. e.g. Communication and coordination between different healthcare providers, Continuity of care between different settings (e.g., hospital to home) and Availability of electronic health records and information sharing. Mostly limited/affected by poor digital infrastructure.

We observe that >80% of contents in Quality of Healthcare and Patient Safety Bill 2025 are already provided for in other legislations and policies within the ministry including; Health Act 2017, National Policy on Patient Safety, Health Worker Safety and Quality of Care, Public Health Act, Clinical Officers Act, Medical Practitioners and Dentists Act, Nurses Act, Kenya Quality Model of Health (KQMH) policy, Medical Laboratory Technicians and Technologists Act, Nutrition and Dieticians Act, PHOTC Act, Pharmacy and Poisons Act, among others.

The Judgement by Judge Wesley Korir of September 2022 directed for amendment of Health Act 2017, which provides a shorter and cost-effective route for its improvement, if need be, without reproducing and duplicating laws that provide for health.

Management and continuous monitoring of Quality of Healthcare is already provided for in several legislations and policies as indicated above, meaning this bill will not change anything as far as quality of healthcare is concerned.

PROBLEM STATEMENT

We have identified the following issues with the bill; -

1. Duplication and Confusion.

-The bill will create confusion and duplication of roles by replicating other Acts e.g. rights and duties under Health Act and Public Health Act provisions among many others.

2. Weak Quality Assurance Framework.

-The biggest problem that has affected quality of care with regard to health facilities has been the wrong designation of health facilities due to weak quality assurance mechanisms which do not provide for verification.

-This bill still retains this problem where one entity registers, licenses and accredits facilities which has led to corruption and the consequent poor quality of health. This is because facilities were allocated erroneous levels that neither matched their resources nor capacity due to lack of an independent verification system.

-A strong and progressive Quality Assurance Mechanism should have a two tier accreditation system, where the relevant regulatory body registers and licenses and then an independent body verifies and accredits.

3. Interference with development of Scopes of Practice.

- Transfer of Mandate on development of Scopes of Practice from regulatory bodies to Director General is retrogressive and will negatively affect quality of health.
- Councils and Boards are better placed to continue with this function since they have a diversity of members representing various fields including trainers, regulators, legal practitioners and practitioners in the relevant field, which provides a better and informed forum for development of progressive Scopes of Practice.

4. Duplication of Roles

The Judgement of September 2022 on Health Act interpreted KHPOA to be the ultimate body responsible for Quality of Healthcare in Kenya. There is therefore no need to bring in another SAGA when KHPOA can be improved to serve its purpose. Lack of operationalization of KHPOA after 7 years has been a deliberate act to create a perception that it can't serve its purpose.

5. Kakamega Cabinet Resolution of Feb 2025.

The Kakamega cabinet resolution 2025 directed for merger, dissolution or declassification in view of the tight fiscal space within the reality of rising debt burden. Introduction of another SAGA that serves the role of KHPOA goes against the principles of that resolution and is totally unnecessary.

We submit that the real issues that threaten quality of healthcare currently include;

- Financing – inadequate budgetary allocation to health
- Staff shortage – there is no clear framework on resolving HRH staff shortages
- Service disruption from perennial strikes
- Poor digital infrastructure.
- Demoralization and demotivation of health workers.
- Poor coordination between National and County Governments.
- Political interference.
- Over legislation without the required implementation

RECOMMENDATIONS

1. Withdrawal of The Quality of Healthcare and Patient Safety Bill 2025 and instead amends Health Act 2017.

2. Alignment of budgetary allocation to health with Abuja Declaration of 2001 that provided for allocation of 15% of the total budget.

3. Development of a framework for annual employment of 12,000 health workers in line with Kenya's Human Resources for Health Commitments at the 2013 Third Global WHO HRH Forum in Brazil.

4. Fast tracking of amendments to the Health Act and designation of KHPOA as the Quality of Healthcare Authority in line with Justice Wesley Korir's Judgement of September 2022.

5. Full Implementation of Health Act 2017 by fully operationalizing Kenya Health Professionals and Oversight Authority and Kenya Health Human Resources Advisory Council.

6. Negotiation, Completion and full implementation of Collective Bargaining Agreements as well as signing Recognition Agreements to reduce service disruption through strikes.

MEMORANDUM ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025 PROVISIONS.	REMARKS	JUSTIFICATION
Definitions; PART 1 ; Preliminary in Health Act No.21 of 2017 "Health care provider" means a person who provides health care services and includes a healthcare professional;"	Retain the definition as is in the Health Act "Health care provider" means a person who provides health care services and includes a healthcare professional;"	A person providing health care services must be trained, licenced and regulated by the relevant regulatory body. The proposed definition is ambiguous and there is need for specificity and clarity
"Health facility" means the whole or part of a public or private institution, building or place, whether for profit or not, that is operated or designed to provide in-patient or out-patient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health service	delete and replace with; "Health facility" means a **health provider** or an entity whether operating from a fixed physical structure or through mobile and digital platforms, that is established for the purpose of providing healthcare services, including hospitals, clinics, pharmacies, medical laboratories, mortuaries, funeral homes and parlours, home care centres, ambulances, mobile medical units, telemedicine services, medical aesthetic	The definition of a **"person" as a facility** is confusing and does not provide the clarity of "natural person" or the "legal person"

	procedures and community health services	
SCOPE OF PRACTICE Patient safety and quality assurance measures. **19.**(1) A health facility shall— (a) implement measures to ensure patient safety and quality of healthcare in their health facility; (b) provide healthcare services or perform a medical procedure for which the health facility or healthcare provider at the health ity is duly qualified and licensed under this Act or any other relevant laws; and (c) adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as prescribed by the Cabinet Secretary on the recommendation of the Director-General. (2) A person who fails to comply with the provisions of this section commits an offence and shall be liable, on conviction, to a fine not exceeding fifty million shillings or to imprisonment for a term not exceeding to ten years, or to both	The establishment of the Scopes of Practice to be retained at the respective regulatory bodies i.e COC, NCK, KMPDC etc. Notably, the **Director-General of Health already serves as a board member** on most of these Councils, ensuring government representation and alignment with national policy. We propose section 19. 1. (c) of the proposed Quality of care and patient safety bill to be amended to read as "Adhere to the scope of practice for the healthcare providers employed or contracted in health facilities as developed by the respective regulatory body and approved by the Cabinet Secretary". A KSh 50 million fine or 10-year imprisonment is grossly excessive. We propose section 19. 2. of the proposed Quality of care and patient safety bill to be amended to read as "A KSh 500,000 thousand fine or 3-year imprisonment"	Each carder is governed by an act of parliament that establishes its regulatory council that is mandated to develop, update and reinforce the various scopes of practice The Scope of Practice for Clinical Officers like any other carder sets forth the legislative and regulatory framework for guiding all Clinical Officers licensed to practice in Kenya to perform their duties safely while ensuring that all patients are protected from harm and that they receive the best possible healthcare to the highest attainable standards. It outlines the key areas of competencies (knowledge, skills and attitude), professional roles and responsibilities for Clinical Officers in practice both at general and specialized levels. A fine/penalty should be procedurally proportionate fair, just and affordable The fine is fixed and is not taking the consideration of the facility level and professional, it also way above as provided in the penal code
KHPOA The Health Act No. 21 of 2017 needs to be amended to restructure and expand the functions of KHPOA, which will give it an accreditation mandate as well as monitoring and ensuring that	We propose a two tier quality assurance system as detailed below; Two Tier Verification framework i. Tier one - registration and licensure by the respective regulatory body ii. Tier two- verification and accreditation	1. Duplication of Roles - The Judgement of September 2022 on Health Act interpreted KHPOA to be the ultimate body responsible for Quality of Healthcare in Kenya. There is therefore no need to bring in another SAGA when

the highest standards of health services are maintained through 'quality of care inspections and accreditation ' as provided under article 43 of the constitution.	by a different body (suggested to be KHPOA), before empanelment. and; - Restructuring Kenya Health Professionals Oversight Authority to expand its mandate into accreditation and quality of care.	KHPOA can be improved to serve its purpose. Lack of operationalization of KHPOA after 7 years has been a deliberate act to create a perception that it can't serve its purpose. 2. Kakamega Cabinet Resolution Feb 2025. - The Kakamega cabinet resolution 2025 directed for merger, dissolution or declassification to reduce financial demand. - Introduction of another SAGA that serves the role of KHPOA goe against the principles of that resolution.
Amendment of section 20 of Cap.253E. **35.** Section 20 of the Clinical Officers (Training, Registration and Licensing) Act is amended by— (a) deleting subsection (5); (b) deleting subsection (6); (c) deleting subsection (7); and (d) deleting subsection (8). Repeal of section 23 of Cap. 253E. **36.** The Clinical Officers (Training, Registration and Licensing) Act is amended by repealing section 23. Amendment of section 23A of Cap. 253E. **37.** Section 23A of the Clinical Officers (Training, Registration and Licensing) Act is amended by deleting the words "and every health institution shall in each year insure the health institution against professional liability of its staff" appearing immediately after the word "cover"	Retaining this in the Clinical Officers Act No. 20 of 2017 as is.	Regulation of Health facilities by the relevant regulatory body which also regulates training and practice of the relevant professionals is better placed to monitor quality service delivery since they understand their scope. In the Two Tier Verification framework for quality purposes i.e i. Tier one - registration and licensure by the respective regulatory body ii. Tier two- verification and accreditatio by a different body (suggested to be KHPOA), before empanelment. so therefore the functions of the Council should be retained as this framework caters for quality
SHA	Retain these sections as currently provided	No justification provided to support their

Amendment of section 2 of No.16 of 2023. **38.** Section 2 of the Social Health Insurance Act is amended by— (a) deleting the definition of the term "Dispute Resolution Tribunal"; and (b) inserting the following new definition in its proper alphabetical sequence—"tribunal" means the Health Care Tribunal established under section 86 of the Quality Health Care and Patient Safety Act. Amendment of section 33 of No.16 of 2023. Section 33 of the Social Health Insurance Act is amended in subsection (5) by deleting the words "Dispute Resolution". Repeal of the heading of Part VIII of No.16 of 2023. **40.** The Social Health Insurance Act is amended by repealing the heading of PART VII. Amendment of section 43 of No.16 of 2023. **41.** Section 43 of the Social Health Insurance Act is amended in subsection (1) by deleting the words "Dispute Resolution". Repeal of section 44 of No.16 of 2023. **42.** The Social Health Insurance Act is amended by repealing section 44. Repeal of section 45 of No.16 of 2023. The Social Health Insurance Act is amended by repealing section 45.	under the Social Health Insurance Act.	amendment/deletion.
BOARD COMPOSITION (a) a chairperson appointed by the President; (b) the Principal Secretary in the Ministry for the time being responsible for matters relating to 19 The Quality Healthcare and Patient Safety Bill, 2025 quality of healthcare standards or a representative designated in writing; (c) the Principal Secretary for the National	Improve representation of County Governments to include; 1. One member nominated by the forum for County Secretaries 2. One member nominated by the forum for CECM Health 3. One member nominated by the forum for Chief Officers	Has only one representative of County Governments yet County Governments manage > 90% of facilities.

Treasury or a representative designated in writing; (d) the Director-General; (e) one person appointed by the Cabinet Secretary, not being a Governor, nominated by the Council of County Governors with knowledge in matters of health, quality management and quality improvement; (f) two persons appointed by the Cabinet Secretary, not being public officers, nominated by— (i) the consortium of healthcare providers; and (ii) a patients' association in Kenya; and (g) one person appointed by the Cabinet Secretary with expertise in quality healthcare for patients; and (h) the Chief Executive Officer, who shall be an ex officio member of the Board.		

RECOMMENDATION

- **Withdraw the proposed Bill and Amend Health Act 2017**

KENYA MEDICAL PRACTITIONERS AND DENTISTS COUNCIL

SUBMISSION TO THE NATIONAL ASSEMBLY

ON THE

QUALITY HEALTHCARE AND PATIENT SAFETY BILL, (NATIONAL ASSEMBLY BILL NO. 42 OF 2025)

MARCH, 2026

Kenya Medical Practitioners and Dentists Council
KMPDC House
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SUBMISSIONS BY THE KENYA MEDICAL PRACTITIONERS AND DENTISTS COUNCIL ON THE QUALITY HEALTHCARE AND PATIENTS SAFETY BILL (NATIONAL ASSEMBLY BILL NO. 42 OF 2025)

1. INTRODUCTION

The Kenya Medical Practitioner and Dentists Council (hereinafter referred to as "Council" or "KMPDC") is established as a statutory body under Section 3 of the Medical Practitioners and Dentists Act (Cap 253) with the mandate to regulate the training and practice of medicine, dentistry and community oral health within the Republic of Kenya. The Council is also mandated by CAP 253 to regulate health facilities in the country.

The Council has reviewed the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 42 of 2025) and presents this submission to provide input on specific provisions that may affect the regulatory framework established under the Medical Practitioners and Dentists Act (Cap 253). The submission is intended to support a clear and consistent legislative approach to healthcare regulation in Kenya.

The Council's recommendations focus on proposed amendments that touch on critical areas such as the regulation of internship training, inspection of medical and dental schools, licensing of practitioners, and enforcement mechanisms. KMPDC notes that some of the proposed changes could affect its ability to effectively discharge its mandate, particularly with regard to training oversight and compliance with regional obligations under the East African Community frameworks.

This submission sets out specific clauses where amendments or retention of existing provisions are proposed, together with the rationale for each recommendation. The Council remains available for further engagement to ensure alignment between the objectives of the draft Bill and the existing legal and institutional framework.

2. SUMMARY OF KMPDC'S SUBMISSIONS

2.1. Internship Oversight

- The Bill proposes removing KMPDC's role in inspecting and accrediting facilities for internship and training.
- KMPDC states that internship is part of the training continuum and should remain under its regulation.
- This is so that KMPDC can ascertain the quality and level of internship training prior to their registration and licensing as medical, dental and community oral health practitioners.
- Devoid of this, the Council shall consider a post-internship or pre-registration examination for all practitioners.

2.2. Definition of Private Practice

- KMPDC recommends that the regulation of private practice for medical, dental, and community oral health practitioners should remain under its authority.

2.3. Inspections – Section 4A

- The Bill removes the word "inspections" from the Inspections, Licensing, Finance and General-Purpose Committee.
- KMPDC recommends retaining it, noting that it conducts inspections of medical and dental schools in line with East African Community (EAC) agreements on recognition of qualifications.
- This is also to allow KMPDC to inspect teaching hospitals (as part of the training), internship training centers and post-graduate collegiate centers.

2.4. Regulation of Training – Section 5

- The Bill deletes provisions on KMPDC's role in regulating training.
- KMPDC recommends retaining these provisions to continue overseeing medical and dental training, including internships, in line with EAC agreements.

2.5. Recovery of Fees – Section 17

- The Bill repeals Section 17 on recovery of fees by practitioners.

- KMPDC proposes amending instead, to specify that only practitioners licensed under Section 14 may recover fees.

2.6. Transition

- Under Section 26 (2), it is the Council's request that the staff from KMPDC who handle matters pertaining to regulation of health facilities, who may be affected, be considered for transition to the Quality Healthcare and Patient Safety Authority within their existing terms and conditions.
- That, in the event the affected parties are not considered for transition, a structured and orderly exit framework be adopted to facilitate their disengagement.
- That provision be made for appropriate financial support to enable such separation, including severance or separation payments as may be applicable.
- That adequate budgetary allocation be made to cater for liabilities arising from the termination of existing contracts.
- That such allocation covers all attendant costs, including contractual penalties, settlement sums, and any other obligations in accordance with the terms of the respective agreements and applicable law.

3. SUBMISSION ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL

The Council hereby submits as follows:

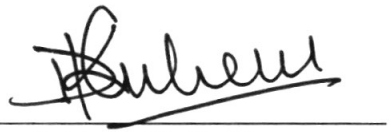
PART NO	MARGINAL NOTE	SECTION NO/ PROVISION NO	PROVISION IN THE BILL	RECOMMENDATION	JUSTIFICATION
PART III – ADMINISTRATION OF QUALITY OF HEALTHCARE	**Functions of the Authority**	**Section No. 28 (l)**	The functions of the Authority shall be to— (l) inspect and accredit health facilities for purposes of internship and training;	Delete paragraph (l)	Internship forms part of the continuum of the regulation of the training of medical and dental students. By dint of this provision, KMPDC will not be able to effectively ascertain the quality of internship training for medical, dental and community oral health practitioners. The Council may consider administering a post-internship examination/pre-registration examination.
SECOND SCHEDULE	**Amendment of Section 2 of CAP 253**	**Schedule Provision No. 19.**	Section 2 of the Medical Practitioners and Dentists Act is amended— (b) in the definition of the term "private practitioner" by deleting the expression "section 15" and substituting therefor the words "the Quality of Health Care and Patient Safety Act".	Section 2 of the Medical Practitioners and Dentists Act is amended— (b) in the definition of the term "private practitioner" by deleting the expression "as either a medical practitioner or a dentist who is also licensed under section 15 to practise" and substituting therefor the words "who practices"	Private practice is centered around the **practice** of the medical, dental or community oral health practitioner. This should be left to KMPDC to regulate the private practice of medicine, dentistry and community oral health.

PART NO	MARGINAL NOTE	SECTION NO/ PROVISION NO	PROVISION IN THE BILL	RECOMMENDATION	JUSTIFICATION
	Amendment of Section 4 of CAP 253	**Schedule Provision No. 20 (c)**	Section 4 of the Medical Practitioners and Dentists Act is amended by – (c) deleting paragraph (f);	Do not delete Section 4(f) from CAP 253	Internship forms part of the continuum of the regulation of the training of medical and dental students. By dint of this provision, KMPDC will not be able to effectively ascertain the quality of internship training for medical, dental and community oral health practitioners. The Council may consider administering a post-internship examination/pre-registration examination.
	Amendment of Section 4 of CAP 253	**Schedule Provision No. 21**	Section 4A of the Medical Practitioners and Dentists Act is amended in subsection (1) by deleting the word "inspections" appearing in paragraph (c).	Do not delete the word "inspections" from Section 4A of CAP 253	KMPDC along with its sister regulatory bodies within the East African Community carry out inspection of medical and dental schools in fulfillment of the EAC Treaty and the EAC Common Market protocol provisions on the free movement of goods and professional services across the region. As per the Mutual Recognition Agreement, KMPDC is the competent authority in Kenya to implement the reciprocal recognition provisions.

PART NO	MARGINAL NOTE	SECTION NO/ PROVISION NO	PROVISION IN THE BILL	RECOMMENDATION	JUSTIFICATION
	Amendment of Section 5 of CAP 253	**Schedule Provision No. 22**	Section 5 of the Medical Practitioners and Dentists Act is amended in subsection (3) by— (a) deleting paragraph (g); (b) deleting paragraph (h); and (c) deleting paragraph (i);	Do not delete Section 5(2) (g) and (h) from CAP 253	This is to cater for KMPDC to regulate the training of medical and dental students as provided for in the EAC Mutual Recognition Agreement. To allow KMPDC to regulate the training of medical and dental interns due to the fact that Internship forms part of the continuum of training of a practitioner to be.
	Amendment of Section 17 of CAP 253	**Schedule Provision No. 17**	The Medical Practitioners and Dentists Act is amended by repealing section 17.	Section 17 of CAP 253 should not be repealed, but should be amended to read as follows: **17. No fees recoverable unless person licensed under section 14** No person shall be entitled to recover a charge for medical or surgical advice or attendance, or for the performance of an operation as a medical practitioner or dentist, or for medicine which he has prescribed and supplied as a medical practitioner or dentist, unless he is at the time appropriately licensed under section 14.	This focuses on the recovery of fees by a practitioner only if he is licensed.

PART NO	MARGINAL NOTE	SECTION NO/ PROVISION NO	PROVISION IN THE BILL	RECOMMENDATION	JUSTIFICATION
	Amendment of Section 26 of CAP 253	**Not considered in the Bill**	Not considered in the Bill	Section 26 of the Medical Practitioners and Dentists Act is amended by— (a) adding subsection (5) that reads as follows: (5) That the staff from KMPDC who handle matters pertaining to regulation of health facilities, who may be affected, be considered for transition to the Quality Healthcare and Patient Safety Authority within their existing terms and conditions. (6) Where any staff are not transitioned under this Act, the Cabinet Secretary for Health in consultation with the Council shall ensure an orderly disengagement. (7) Provision shall be made for appropriate separation benefits, including severance or other lawful payments. (8) Adequate funding shall be provided to settle liabilities arising from the termination or variation of affected contracts, including any penalties or compensation due under applicable law.	This is so that the staff currently handling the function of registration, licensing, inspection and disciplinary matters of health facilities will not have any loss occasioned by the transfer to function.

Submitted on this 19th day of March, 2026:



Date: 19/03/2026

DR. DAVID G. KARIUKI
CHIEF EXECUTIVE OFFICER
KENYA MEDICAL PRACTITIONERS AND DENTISTS COUNCIL

Adan Gindicha
to Commit to the DC on Health.
22/9/25

19/09/25

MEMORANDUM TO PARLIAMENT

Re: *The Quality Healthcare and Patient Safety Bill, 2025* (Gazetted, National Assembly Bill No. 41 of 2025)
From: Dr. Richard Mogeni, Consultant Obstetrician & Gynaecologist
To: The Departmental Committee on Health, National Assembly
Date: 5th September,2025

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1. Position Summary

I appreciate Parliament's commitment to improving the quality of healthcare in Kenya. However, after reviewing the *Quality Healthcare and Patient Safety Bill, 2025*, I am firmly of the view that **patient safety and quality improvement should not be legislated in a punitive manner**.

The Bill's approach risks creating a culture of fear and concealment, undermining systems such as *Maternal and Perinatal Death Surveillance and Response (MPDSR)*, which depend on open disclosure. Instead of genuine quality improvement, we may see superficial compliance, defensive medicine, and reluctance to care for high-risk patients.

Quality is best advanced by **strengthening clinical governance**, supporting professional self-regulation, and holding government accountable for systemic enablers — staffing, drugs, equipment, and infrastructure.

---

2. Concerns in Practice

1. **Criminalisation of Quality Failures**
    - Clause 19(2) imposes harsh penalties (up to KES 50M or 10 years imprisonment).
    - In practice, most adverse outcomes stem from systemic failures, not wilful misconduct. Criminalising them will silence reporting and cripple MPDSR.
2. **Linking Financing to Accreditation Scores**
    - Clauses 23(4) and 68–70 tie SHI access to quality benchmarks.
    - Facilities in resource-poor counties will be penalised for government failures beyond their control. Patients may lose access to care.
3. **New Bureaucracy and Duplication**

Hassan Arale
P/S bring to the attention of the Committee.
22/09/2025

    - Clauses 27–29 and 74–81 create a new Authority with sweeping powers, duplicating existing regulators.
    - This risks more bureaucracy, higher costs, and unfair burdens on private and faith-based facilities.
4. **Lack of Protection for Learning Systems**
    - The Bill is silent on confidentiality of MPDSR, morbidity & mortality reviews, or peer reporting.
    - Without legal protection, clinicians will withdraw from these essential learning processes.
5. **Government Accountability is Missing**
    - The Bill places penalties on providers but not on government when shortages, stock-outs, or poor infrastructure directly cause preventable deaths.

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3. Way Forward

- **Strengthen Clinical Governance:** Institutionalise quality improvement teams, morbidity & mortality reviews, and internal dashboards in every facility.
- **Protect Learning Systems:** Legally guarantee confidentiality of MPDSR and internal QI processes.
- **Empower Professional Self-Regulation:** Recognise specialist societies and councils as custodians of standards and peer review.
- **Use Incentives, Not Punishment:** Link accreditation to phased support, mentoring, and performance-based incentives.
- **Hold Government Accountable:** Enforce obligations on staffing, drugs, supplies, and infrastructure.

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4. International Lessons

- **UK NHS:** Shifted from punitive inspection to a *Just Culture* focused on learning.
- **South Africa (SafeCare):** Voluntary, stepwise accreditation supported by ISQua.
- **Rwanda:** Performance-based financing tied to outcomes, backed by supervision and support.

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5. Conclusion

The Bill's intentions are commendable, but in its current form, it risks doing more harm than good. A punitive legal framework will undermine transparency, weaken MPDSR, and increase bureaucracy.

I respectfully recommend that Parliament:

- **Withdraw or substantially amend the Bill** in its current form.
- Adopt a **National Policy on Patient Safety and Clinical Governance** anchored in professional leadership, non-punitive reporting, and systemic accountability.

Annex: Suggested Draft Amendments

Amendment 1 — Clause 19(2): Criminal Penalties
Replace with:

"A person who wilfully or recklessly causes harm to a patient by an act or omission amounting to gross negligence or criminal conduct shall be liable under the Penal Code and relevant professional disciplinary procedures.
Non-compliance with administrative requirements shall attract corrective action plans, suspension of accreditation, or fines as may be prescribed."

Amendment 2 — New Clause: Confidentiality of Learning Systems
Insert after Clause 21:

"Records from MPDSR, morbidity & mortality reviews, peer review sessions, or quality improvement forums shall be confidential and inadmissible in criminal or enforcement proceedings, except where independent evidence of wilful misconduct exists."

Amendment 3 — Clause 23(4): Accreditation and SHI Access
Replace with:

"Access to the Social Health Insurance Fund shall be based on minimum safety standards. Facilities not meeting higher benchmarks shall be given phased compliance plans and technical support before suspension or withdrawal is considered."

Amendment 4 — Clauses 27–29: The Authority

"The Authority shall act primarily as a supportive accreditation and capacity-building body. Its Board shall include representatives from regulatory councils and at least three specialist professional societies."

Amendment 5 — Clauses 68–70: Penalties

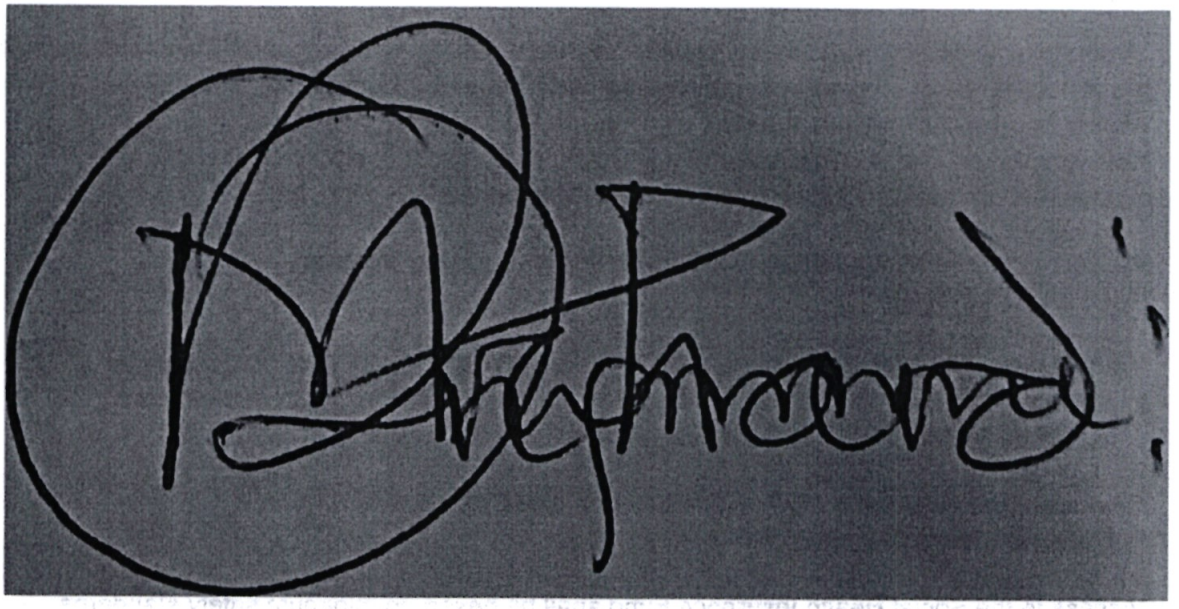
"Failure to meet quality targets shall first attract supportive interventions (improvement plans, technical support, mentoring). Penalties may apply only where a facility persistently refuses corrective measures."

Amendment 6 — New Clause: Government Accountability

"The National and County Governments shall ensure adequate staffing, medicines, equipment, and infrastructure. Where government failures materially contribute to poor outcomes, the responsible entity shall be held accountable through reporting to Parliament and sanctions prescribed in regulations."

Amendment 7 — Clauses 74–81: Inspection Powers

"Inspections shall be conducted by teams including clinical experts. Reports shall distinguish between failures caused by government under-resourcing and those attributable to facility management."



Signed:

Dr. Richard Mogeni
Consultant Obstetrician & Gynaecologist,Masters in the Biotechnology of Human Assisted Reproduction and Embryology(IVI Valencia),Trainer or Trainers Joint Commission International on Patient Safety
Deputy Director, Reproductive Health and Head of Maternal-Fetal Medicine, Moi Teaching and Referral Hospital
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richmogus@gmail.com

(i) DDC
&
19/9/25

(ii)
Adan Gindicha
Pls deal
22/9/25

DIRECTORATE OF DEPARTMENTAL COMMITTEES
RECEIVED
22 SEP 2025

KENYA MEDICAL PRACTITIONERS AND DENTISTS COUNCIL
Governing Quality Healthcare

KENYA MEDICAL PRACTITIONERS AND DENTISTS COUNCIL

SUBMISSION TO THE NATIONAL ASSEMBLY

ON THE

QUALITY HEALTHCARE AND PATIENT SAFETY BILL, (NATIONAL ASSEMBLY BILL NO. 42 OF 2025)

(iii) Mr. Hassan Arale
Please deal
22/09/25

SEPTEMBER, 2025

Kenya Medical Practitioners and Dentists Council
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E-Mail: info@kmpdc.go.ke
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NATIONAL ASSEMBLY
RECEIVED
19 SEP 2025
CLERK'S OFFICE
P O Box 41842, NAIROBI

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PART NO	MARGINAL NOTE	SECTION NO/ PROVISION NO	PROVISION IN THE BILL	RECOMMENDATION	JUSTIFICATION
					implement the reciprocal recognition provisions
	Amendment of Section 5 of CAP 253	**Schedule Provision No. 22**	Section 5 of the Medical Practitioners and Dentists Act is amended in subsection (3) by— (a) deleting paragraph (g); (b) deleting paragraph (h); and (c) deleting paragraph (i);	Do not delete Section 5(2) (g) and (h) from CAP 253	This is to cater for KMPDC to regulate the training of medical and dental students as provided for in the EAC Mutual Recognition Agreement. To allow KMPDC to regulate the training of medical and dental interns due to the fact that Internship forms part of the continuum of training of a practitioner to be.
	Amendment of Section 17 of CAP 253	**Schedule Provision No. 17**	The Medical Practitioners and Dentists Act is amended by repealing section 17.	Section 17 of CAP 253 should not be repealed, but should be amended to read as follows: **17. No fees recoverable unless person licensed under section 14** No person shall be entitled to recover a charge for medical or surgical advice or attendance, or for the performance of an operation as a medical practitioner or dentist, or for medicine which he has prescribed and supplied as a medical	This focuses on the recovery of fees by a practitioner only if he is licensed.

PART NO	MARGINAL NOTE	SECTION NO/ PROVISION NO	PROVISION IN THE BILL	RECOMMENDATION	JUSTIFICATION
				practitioner or dentist, unless he is at the time appropriately licensed under section 14.	
	Amendment of Section 26 of CAP 253	Not considered in the bill	Not considered in the bill	Section 26 of the Medical Practitioners and Dentists Act is amended by— (a) adding subsection (5) that reads as follows; (5) That the staff from KMPDC who handle matters pertaining to regulation of health facilities, who may be affected, be considered for transition to the Quality Healthcare and Patient Safety Authority within their existing terms and conditions.	This is so that the staff currently handling the function of registration, licensing, inspection and disciplinary matters of health facilities will not have any loss occasioned by the transfer to function.

Submitted by:

Date: 5th September 2025

DR. DAVID G. KARIUKI
CHIEF EXECUTIVE OFFICER
KENYA MEDICAL PRACTITIONERS AND DENTISTS COUNCIL

MEMORANDUM OF OBJECTS AND REASONS FOR THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

PRESENTED TO

THE NATIONAL ASSEMBLY

SUBMITTED TO
CLERK OF THE NATIONAL ASSEMBLY
PO BOX 41842-00100, NAIROBI

IN THE MATTER OF CONSIDERATION OF THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

From 1 to 7

09th SEPTEMBER 2025

SUBMITTED BY:
DR. JAMES WATHIGO
MPSK, MBA
CHAIRMAN
PHARMACEUTICAL SOCIETY OF KENYA
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.....

DIRECTORATE OF DEPARTMENTAL COMMITTEES
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15 SEP 2025

NATIONAL ASSEMBLY
RECEIVED
15 SEP 2025
DEPUTY CLERK, S. KIOKO
P.O. Box 41842-00100, NAIROBI

1.0 INTRODUCTION, BACKGROUND AND CONTEXT

This memorandum of objects is cited in **CONSIDERATION OF THE PHARMACY AND POISONS (AMENDMENT) BILL, 2024**

2.0 CONSIDERATIONS

NO	CLAUSE	PROPOSAL	JUSTIFICATION
Second Schedule: Consequential Amendments to other Acts			
THE CONSTITUTION OF KENYA. FOURTH SCHEDULE Part 1. NATIONAL GOVERNMENT 27. Health policy.	The Clause proposes the National Government to establish Health Policies in favour of the constitutional rights of every Kenyan.	Focus should on the Cabinet secretary of Health establish and publish the Ministry organogram with directorates aligned to all regulatory bodies and Ministry divisions under each established directorate and secondments to other Ministries departments and agencies.	The constitution justifies organization structures to ensure national government runs seamlessly.
THE CONSTITUTION OF KENYA. FOURTH SCHEDULE Part 2. County health services, including in particular (a) county health facilities and pharmacies; (b) ambulance services; (c) promotion of primary health care;	The Clause proposes the county Government to establish Health services in favour of the constitutional rights of every Kenyan.	Focus should on the CEC of Health establish and publish the Ministry organogram with directorates aligned to all regulatory bodies and Ministry divisions under each established directorate.	The constitution justifies organization structures to ensure county government runs seamlessly.
CAP 241 Health Act & Clause 94 Subsections 2 (q)	Amendment of section 2 of Cap. 241 B deleting the definition of the term "healthcare services" and substituting therefor the following new definition "healthcare services" means the prevention,	All Premises are in the **Addendum 1**	To be aligned with Clause 44 of the Act and Clause 94 Subsection 2 (q). The Food and Drug Administration, the most stringent Health Products authority in the world, places food, Drugs, Medical devices, radiation-emitting products, vaccines, blood, biologicals, animal and veterinary products, cosmetics, and tobacco products, as seen on their website. https://www.fda.gov/ Also European Medicines Agency https://www.ema.europa.eu/en/human-regulatory-overview

	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 healthcare system's routine health services including mortuaries, funeral homes and parlours, home care centres or its emergency medical care services; and 94. (1) The Cabinet Secretary may, in consultation with the Board, make Regulations for the better carrying into effect of the provisions of this Act.(2) Without prejudice to the generality of subsection (1), the Cabinet Secretary shall make Regulations for (q) categories of health facilities.		
CAP 241 Health Act & Clause 94 Subsection 2 (q)	Amendment of section 2 of Cap. 241 A deleting the definition of the term "healthcare services" and substituting therefor the following new definition "health care provider" means the prevention, promotion, education, medical diagnosis, management or alleviation of disease, illness, injury, and other physical and mental impairments in	Aligned and assign all healthcare professionals connected thereof and incidental to the Amendment of CAP 241 Section B, CAP 244, CAP 245 and any other act before the bill is enacted to an act.	To be aligned with Clause 44 of the Act and Clause 94 Subsection 2 (q), CAP 241, Clause 46 Subsection C.

	individuals, delivered by healthcare professionals through the healthcare system's routine health services, including mortuaries, funeral homes and parlours, home care centres or its emergency medical care services.		
Social Protection Act No. 12 of 2025	Clause 29 proposes Social Protection benefits	I propose that inclusion facilities offering healthcare services registered under this clause be included in this bill.	This is to ensure that healthcare provided under the social protection act is uniform with this bill.
PERSONS WITH DISABILITIES ACT NO. 4 OF 2025	Clause 24 proposes right to health for people with disability	Person with disability to include in the interpretation of a patient clause 2	Persons with disabilities act 4 of 2025 clause 2 defines a person with disability as someone who requires long term care. "persons with disabilities" includes persons with long term physical, mental, intellectual, developmental or sensory impairments, including visual, hearing or albinism, which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.
PERSONS WITH DISABILITIES ACT NO. 4 OF 2025	Clause 25 proposes the right of people with disability to participate in Health programmes.	To be included in all the mandates of the act.	To be included in all the mandates of the act.
NO	**CLAUSE**	**PROPOSAL**	**JUSTIFICATION**
Clause 6 (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.	Insert of a New subsection immediately after Clause 6 (G) Subsection H. The provision of this act shall be subject to further control of the Strategic Goods Act.	The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.
Clause 8 Subsection 2 (d)	Respond to medical emergencies and make provision for access to emergency medical care through the national health emergency	Insert of New subsection immediately Clause Subsection 2 (d) Subsection 2 (e) The provision of this act shall be subject to further control of the Strategic	

	communication centre maintained by the Digital Health Agency	Goods Act.	
Clause 46 Subsection C	Evidence that the health facility is to be operated or managed by a healthcare professional registered by a relevant regulatory body;	Insert registered and retained under this act.	This reduces double jeopardy to healthcare professionals paying professional fees to different authorities, and introduction a unified licence.
Clause 46 B	Clause 46 (b) proposes a description of a health facility, specific information or activity, including—	Insert a new subsection after Clause 46 (b) iv. That application must be accompanied by registration of the superintendent of the facility and the superintendent of each department, including speciality clinics, in one unified licence.	This reduces the risk of double jeopardy for healthcare professionals who pay professional fees to different authorities and introduces a unified licence.
Clause 50	Clause 50 Licence	Insert a new subsection two after subsection 1.50. (1) A person who wishes to operate a health facility shall, after being registered under section 47, apply for an annual licence from the Authority. Subsection A person who wishes to operate a health facility shall, after being registered under section 47, apply for an annual licence for all superintendents of each department, each speciality clinic and health professionals	This reduces the risk of double jeopardy for healthcare professionals who pay professional fees to different authorities and introduces a unified licence.
Clause 51	Clause 51 Application for a licence.	Insert of New subsection immediately Clause 51 (F) Subsection G. The provision of this act shall be subject to further control of the Strategic Goods Act.	The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.
Clause 78 Conduct of Inspection	Clause 78 Conduct of Inspection; inspect the conditions and services provided by the health facility; and	Insert Before conducting the inspection, the inspector shall contact the main contact of the facility before entry. Inspection shall be done with the facility representative.	
Clause 78 Conduct of Inspection	Clause 78 Conduct of Inspection; inspect the conditions and	Insert An emergency inspection shall be accompanied by a court warrant.	

	services provided by the health facility; and		
Clause 78 Conduct of Inspection	Clause 78 Conduct of Inspection	Insert new subsection C after Subsection that reports findings shall be shared with the facility, as prescribed in the authorities' charter.	
Clause 22	establish systems for the safe use, storage and administration of health products and technologies, integrated to the Comprehensive Integrated Health Information System established under the Digital Health Act;	Insert of a New subsection immediately after Clause (c) Subsection H. The provision of this act shall be subject to further control of the Strategic Goods Act.	The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.
Clause 51 Application for a licence.	Clause 51 proposes an Application for a licence. (f) particulars of a digital health solution that has been certified by the Digital Health Agency to be used by the health facility;	Insert of a New subsection immediately after Clause (f) Subsection G. The provision of this act shall be subject to further control of the Strategic Goods Act.	The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.
Clause 60	Clause 60 proposes an Application for accreditation to provide proof of listing of the health facility in the facility registry in the Comprehensive Integrated Health Information System established under the Digital Health Act.	Insert of a New subsection immediately after Clause (H) Subsection I. The provision of this act shall be subject to further control of the Strategic Goods Act.	The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.
Clause 70	Clause 70 proposes a Register of health facilities.	Insert Subsection H after G. The provision of this act shall be subject to further control of the Strategic Goods Act.	The Clause qualifies in the interpretation of the act; clause 2; National control goods means strategic goods, and technology, tangible or intangible, that are placed under unilateral controls for reasons of national security, foreign policy, anti-terrorism, crime control or public health and safety.

Addendum 1

1. All marketing authorization holders under the Veterinary Act

2. All distributors of Veterinary products
3. All retailers of veterinary products.
4. Add additional categories to include the
5. All departments and agencies under the Ministry of Health
6. All food processors making production of foods with molecules listed schedules of CAP 244 or promote the word healthy in their label claim.
7. All Health Data Collectors
8. All Health Surveys Outputs
9. All Health Data handlers
10. All Human Wellness Business
11. All LTRS to be registered as single entities, all food processors producing foods with molecules listed in schedules of CAP 244 or promoting the word' healthy' in their label claims.
12. All manufacturers of Schedule 1 and Schedule 2 under Cap 244
13. All ministries with seconded health professionals
14. All nutrition manufacturers and distributors
15. All Physiotherapy Centres
16. All premises with borderline products
17. All Scientific Offices under the Ministry of Health
18. All shops selling borderline products
19. All shops selling borderline products
20. Manufacturers of Schedule 1 and Schedule 2 under CAP 244
21. All shops selling herbal products
22. All shops selling herbal products
23. All Social media companies promoting Health.
24. All sporting camps.
25. All Sporting Facilities
26. All Sporting events.
27. All supermarkets
28. All FMCG traders
29. All traders/ Distributors of schedule 1 and 2 all FCMG traders, Nutrition Manufacturers and Distributors
30. All traders/distributors of Schedule 1 and Schedule 2 under Cap 244
31. Any institution with treatment facilities and rooms
32. Approved schools
33. Colleges with treatment facilities
34. Contractor sites.
35. Cosmetics premises
36. County assembly involved in health committees
37. Data Health Information Companies
38. Digital Health Academies
39. Each local technical representation under CAP 244 pharmacy and poisons
40. Each local technical representative under the Medical Lab Board
41. Each local technical representative under the Veterinary Act premises
42. Each marketing authorization holder under CAP 244
43. Each marketing authorization holder under the Medical Lab Board
44. Food and beverage premises labelled healthy and promoting healthy habits.
45. Health Information Creators
46. Health Information Journalists
47. Human Research Centres
48. Individuals and companies offering home care services
49. In-house Mental rooms
50. Insurance Companies
51. Insurance Processors
52. Kenya National Bureau of Statistics
53. Kenya Population Council
54. Medical Camps
55. Medical Television Shows
56. Members of the national assembly and

57. Ministry of Health
58. Mobile clinics and facilities
59. Offsite public engagement with temporary moving clinics
60. Public benefit organizations
61. Patient focus groups. Radio shows promoting health
62. Rehabilitation and substance recovery centres
63. Primary and secondary schools with any treatment facilities
64. Shops cosmetics and beauty
65. Healthcare workers all shops selling Nutraceuticals
66. Veterinary premises
67. World bodies operating in Kenya, such as the World Health Organization, UNICEF
68. All Tobacco Manufacturers
69. All Tobacco distributors.
70. All radiation-emitting Manufacturers.
71. All radio-emitting distributors.
72. All radio-emitting distributors of testing devices.
73. All Premises registered under the Persons with Disability Act 8 2025
74. All premises registered under the Social Protection Act no 12 of 2025
75. All patient focus groups and public benefit organization registered under the Persons with disability acts number 08 2025

KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

Our Ref: KENAS/LG/01 **9th September 2025**

@ DDC
Please deal.
15/09/25
@ Hon. Njoroge
Send
15/9/25

Mr. Samuel Njoroge, CBS
Clerk of the National Assembly
Parliament Buildings
P.O. Box 41842
NAIROBI

Dear Hon. Njoroge,

SUBMISSION OF KENYA ACCREDITATION SERVICE COMMENTS ON THE DRAFT QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

The Kenya Accreditation Service (KENAS) hereby submits the following consolidated comments on the Draft Quality Healthcare and Patient Safety Bill, 2025, currently under consideration in Parliament.

As Kenya's sole national accreditation body, established under the Kenya Accreditation Service Act CAP 496A, the Service plays a pivotal role in ensuring the competence, impartiality, and credibility of conformity assessment processes across sectors, including healthcare.

Our proposals aim to: Align the bill with international best practices as conceptualized in ISO/IEC standards; harmonize the draft law with existing legislation mandating accreditation of conformity assessment bodies; and strengthen Kenya's national quality and patient safety infrastructure in a coherent and sustainable manner.

Should the National Assembly require further technical inputs, including participation in stakeholder consultations the service is ready to provide further input towards ensuring that the law attains a greater good for the people of Kenya.

We appreciate your consideration of our inputs and remain committed to advancing a healthcare quality framework that assures safe, reliable, and globally recognized services for all Kenyans.

Yours Sincerely,

Dr. Walter Ongeti
CHIEF EXECUTIVE OFFICER
WON/wny

NATIONAL ASSEMBLY
RECEIVED
10 SEP 2025
DEPUTY CLERK
P.O. BOX 41842-00100 NAIROBI

DIRECTORATE OF DEPARTMENTAL COMMITTEES
RECEIVED
15 SEP 2025

CC: Dr. Juma Mukhwana, CBS
Principal Secretary
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KENAS Delivering Trust | KENYA ACCREDITATION SERVICE

COMMENTS ON THE DRAFT QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

No.	Provision	Proposed Amendment	Justification for the Proposed Amendment
1.	**Section 2. Interpretation**	Substitute the phrase ***accreditation for quality of healthcare*** with ***certification for quality healthcare***	The nature of accreditation defined in the section and assigned to the authority under Section 28(f) in the Bill is third party attestation of competence, to international standards for healthcare facilities. This is a mandate allocated to National Accreditation Bodies (in Kenya, the Kenya Accreditation Service) under ISO/IEC 17000 Standards series more specifically ISO/IEC 17011:2012 which is domesticated in Kenya through the Kenya Accreditation Service Act CAP 497A Laws of Kenya. The Quality Healthcare and Patient Safety Authority may therefore be a certifier certifying quality healthcare to ISO 7101:2023 (Management systems for healthcare organizations) or a locally established standard but not an accreditation body under ISO/IEC 17000 Standards series. The change will ensure that the Bill does not conflict with the Kenya accreditation Service Act and tat there is

KENAS Delivering Trust | KENYA ACCREDITATION SERVICE

No.	Provision	Proposed Amendment	Justification for the Proposed Amendment
			coherence with the established principles on structuring of national quality infrastructure institutions
2.	**New**	Introduce a definition of the term accreditation reading as follows "Accreditation" means an attestation by the Service established under the Kenya accreditation Service Act that a medical laboratory is competent to carry out specific conformity assessment tasks	Defines the word accreditation as shall be used under te proposed section 46(cc), 61(e)
3.	**Section 23 Functions of the Authority (Subsection 4)**	Substitute the word *accreditation* with *certification*	Refer to the justification in respect to **Section 2** row 1 above
4.	**Section 28 Quality improvement (Paragraph (f))**		
5.	**PART IV— REGISTRATION, LICENSING AND ACCREDITATION OF HEALTH FACILITIES (Section 58, 59, 60,61,62,63,64,65 & 66)**		
6.	**Section 46**	Introduce a new paragraph after paragraph (c) worded as follows; ***(cc) evidence that the health facility laboratory is***	Medical Laboratories are conformity assessment bodies. Under Section 10A (1) of the Kenya Accreditation Service Act, all Conformity assessment

KENAS Delivering Trust | KENYA ACCREDITATION SERVICE

No.	Provision	Proposed Amendment	Justification for the Proposed Amendment
		accredited under the Kenya Accreditation Service Act.	bodies shall be accredited under the Act. For medical laboratories, this accreditation is mandatory to ascertain compliance to ISO 15189 to ensure global alignment; addresses high-risk areas; strengthens patient safety; preserve Kenya's international credibility; and assist the authority carry out its regulatory mandate by covering existing gaps
7.	**Section 61(e) – Healthcare Standards**	Amend the subsection to read as follows; (e) accreditation of medical laboratory.	Ensures global alignment; addresses high-risk areas; strengthens patient safety; preserves Kenya's international credibility; closes regulatory gaps.
8.	**Section 56**	Introduce a new subsection after subsection (1)(a) to read as follows (aa) its medical laboratory is suspended or withdrawn from accreditation under the Kenya accreditation service Act.	This will facilitate a one government approach in ensuring quality in healthcare wherein sanctions for noncompliance to quality requirements will attract similar consequences.

Dr. Walter Ongeti
CHIEF EXECUTIVE OFFICER
WON/wny

D/DCC
① Please deal.
15/09/25

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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When replying please quote our ref No.:

② Hassan Arale
Seen
15/9/25

Pharmacy & Poisons Board Hse
Along Lenana Road
P.O. Box 27663-00506
NAIROBI

PPB/PAR/VOL.II/LET/35/25

5th September, 2025

The Clerk
National Assembly
P.O. Box 41842-00100
NAIROBI

Dear Sir,

RE: MEMORANDUM ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025; PROPOSED AMENDMENTS TO THE PHARMACY AND POISONS ACT (CAP 244)

A. Introduction

Reference is made to the above subject matter and the invitation from the National Assembly published on 22nd August 2025 inviting submission of Memoranda regarding the Quality Healthcare and Patient Safety Bill, No 4 of 2025.

The Pharmacy and Poisons Board ("**the Board**"), is a statutory body and the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act, Cap. 244 of the Laws of Kenya (hereinafter "**the Act**"), mandated to regulate the practice of pharmacy and ensure the quality, safety, and efficacy of medicines and health technologies available to the public.

In light of the above, the Board hereby submits this memorandum highlighting comments and suggestion regarding the proposals in the draft Bill specifically, those outlined under the consequential amendments. The same is analyzed against the potential resultant effect to the implementation of the Act as it pertains regulatory authority and the broader pharmaceutical governance framework.

The submissions are aimed at offering constructive guidance to ensure alignment with established legal structures, international best practices, and Kenya's public health goals.

B. The practical challenges facing PPB if the Bill is enacted in the current form.

i. Non-compliance with Global Regulatory Standards

The Board, being the regulator for health products and technologies, must be ranked with other similar regulators by the World health Organization (WHO) and accordingly designated a maturity level based on an established criteria known as the Global Benchmarking Tool (GBT).

A strong regulator that meets international standards for quality, safety and efficacy is designated under Maturity Level 1 (ML.1) . The Board seeks to attain ML.3 which would translate to the ability to independently regulate medical products in accordance with the global standards. The assessment is focused on the following nine essential regulatory areas which must be domiciled within a single regulator;

1. National Regulatory System
2. Registration and Marketing Authorization
3. Vigilance
4. Market Surveillance and Control
5. **Licensing Premises**
6. Regulatory Inspections
7. Laboratory Access and Testing
8. Clinical Trials Oversight
9. National Lot Release

ii. Ongoing WHO GBT Assessment

Currently, the Board being the regulator for Kenya's health products, is undergoing the WHO assessment seeking to determine how it is effectively undertaking the aforementioned regulatory functions towards ensuring quality, safety and efficacy of health products and technologies within the country.

The proposed Bill seeks to relieve the PPB of some key regulatory functions as outlined herein below with the resultant effect that it will not have the capacity to effectively cover all regulatory areas as required by WHO and global standards.

The matrix below outlines the effect of the proposed legislative changes on the Act in line with the Consequential Amendments thereto;

Section	Current Provision (Before Amendment)	Proposed Change	Implication/Effect
Section 3B(2)(j)	Mandates PPB to inspect and license all manufacturing premises, importing and exporting agents, wholesalers and distributors, ~~pharmacies, including those in hospitals and clinics, and other retail outlets~~	**Deleted**.	The need for the PPB to inspect and license pharmacies including those in hospitals and clinics is to ensure compliance. The enforcement of both standards and requirement ensure there is synergy in seeking to ensure maintenance of high quality standards in practice of pharmacy. It is a key regulatory function outlined by WHO on licensing function of a regulator.
Section 3B (3) i	Approve and license the premises for the practice by pharmacists and pharmaceutical technologists under this Act	**Deleted**	The justification in having the Board to approve and license the premises for the pharmacist and pharmaceutical technologist also ensures synergy in enforcement of standards. It is a key regulatory function outlined by WHO on licensing function of a regulator.
Section 20	Provides for pharmacists to display name and registration certificate	**Repealed**	The need for display of registration and enrollment certificate is to ensure effective enforcement so that only the duly licensed professionals superintend premises. It further acts as a mechanisms to guarantee access to information. It is a key regulatory function outlined by WHO on licensing function of a regulator.
Section 23	Provides for **registration of premises for pharmacist and Pharmaceutical Technologists** and related provisions.	**Repealed**.	The registration of premises is critical in enforcement. The products must be held by duly qualified professionals. It is a key regulatory function outlined by WHO on licensing function of a regulator.

Section 23A	Establishes the Board's power to close premises **in specific situations.**	**Repealed.**	May pose imminent risk to public health and safety by creating a regulatory gap that weakens oversight in non-compliant premises, exposing the public to unsafe practices.
Section 44 (1) mb	Powers of the Board in consultation with the Cabinet Secretary to make Rules on the standards and practice of pharmacy	**Deleted**	The provision is critical for the Board in outlining the standards and practice of pharmacy. It is a key regulatory function outlined by WHO on licensing function of a regulator.

C. Conclusion

Currently, the Board has aligned its mandate with these global standards, ensuring Kenya's recognition as a competent regulator currently operating at Maturity Level 2. Fragmentation of these roles and transferring oversight to a new Authority, risks establishing an institution with limited technical expertise, institutional memory, or capacity to meet GBT requirements.

It is thus critical to ensure that the nine regulatory areas remain domiciled with the regulator (the Board) in compliance with global best practices. The ranking of the Board to a ML.3 will guarantee investor confidence and improve local manufacturing as the quality, safety and efficacy of health products can be guaranteed.

In view of the highlighted practical challenges on the proposed provisions of the Bill on the regulatory mandate of the Board, the National Assembly is hereby urged to take the submissions on this Memoranda into consideration.

Compiled by;

Dr. F. M. Siyoi
CHIEF EXECUTIVE OFFICER

Copy to: **Cabinet Secretary**
Ministry of Health
P.O Box 30016-00100
NAIROBI

Principal Secretary
State Department for Public Health and
Professional Standards
Ministry of Health
P.O Box 30016-00100
NAIROBI

Kenya Healthcare Federation
The Health Sector Board of KEPSA
2nd Floor, Kedong House, Lenana Road/Ralph Bunche Road
ction

DLDC Please deal. 08/09/25

Hassan Khalif Deal 4/9/25

Kenya Healthcare Federation

Kenya Healthcare Federation (KHF) is the Health Sector Board of the Kenya Private Sector Alliance (KEPSA). Founded in 2004, KHF serves as the Apex body in healthcare delivery which convenes all players across the Healthcare ecosystem such as healthcare providers (Hospitals), associations, manufacturers and suppliers, insurers and financiers, technology firms, and other ecosystem partners to promote a resilient, ethical and high-quality health system. Through evidence-based advocacy, structured public–private dialogue, and collaborative initiatives, KHF works to advance access, quality, efficiency and innovation across the health sector.

OUR SUBMISSIONS: **Quality Health Care and Patient Safety 2025**

PART A- GENERAL COMMENTS
• The term "patient safety" is not defined in the bill. The interpretation of patient safety should be premised in the bill in order to assure the attainment of the objective of the bill as set out in clause 3 which is "to guarantee patient rights and patient safety" and equally set parameters that ascertain safety of patients in medical institutions. • The proposed Quality Health Care and Patient Safety Authority is granted extensive powers across registration, licensing, inspection, enforcement, accreditation, penalty imposition, and linkage to Social Health Insurance access without corresponding accountability mechanisms. Even internal safeguards, such as requirement for multi-stakeholder panels, cross-checks with professional councils, or audit transparency have not been adequately reinforced in these proposed regulations. • The bill should establish a well-structured board composition for the Authority, ensuring inclusive representation of all stakeholders within the health sector including private sector entities to promote effective oversight, balanced governance, and sector-wide accountability. • The Authority's mandate appears to extend into human resource management, professional conduct and training which fall squarely under existing professional regulators and the Ministry of Health's HRH units. For example, clauses around verifying individual licensure, enforcing training obligations, and inspecting for internship suitability duplicate and confuse mandates under KMPDC, NCK, and allied Acts.

- Recommendation: Limit the Authority's Mandate
  - To improve clarity and effectiveness, the Authority's functions should be strictly limited to:
  - Oversight of health facility infrastructure and operations
  - Development of quality of care standards at facility level
  - Coordination and monitoring of patient safety systems and outcomes
  - Not regulate individual professionals, training programs, or licensure, which are better left to the existing constitutional and legal bodies.
- The Bill lacks comprehensive mechanisms for routine reporting and analysis of medical errors and near misses, as well as structured learning systems that support continuous quality improvement. Additionally, it does not provide for patient engagement strategies or feedback loops, nor does it outline scalable and tiered quality frameworks suitable for both large and small healthcare facilities.
- The Bill does speak to the role of the Authority and Health Facilities in establishing safe work environment for the healthcare professionals in the facilities which is a key input in quality of care and patient safety frameworks, this should also include blame free culture and an incident reporting mechanism that is free from victimization of the healthcare professionals.
- Risk of regulatory overload without supportive infrastructure due to introduction of multiple new obligations—mandatory indemnity insurance, accreditation-linked reimbursement, regular inspections etc. without providing capacity building, funding, or tools to support implementation.
- In line with international best practice, the role of accreditation and certification needs to be separated from the role of registration and licensing of health care facilities. Accreditation needs to be done by an independent entity, whereas the authority provides oversight e.g., KENAS provides oversight to Conformity assessment bodies in Kenya and the authority oversights KENAS *Ref from accreditation framework for Health sector Kenya 2019*. These assessments bodies can then share the data and results from the facilities with the authority for use of empanelment. The authority could in addition identify and engage independent certification bodies that would support the facilities in the accreditation process using the existing and approved quality of healthcare standards.

- An equalization framework needs to be established by the authority for recognition of other certification frameworks and international standards aligned to KQMH framework. This will ensure that global standards and best practices are recognized and integrated into the national healthcare system.

- Upon licensing, facilities are free to choose existing and recognized quality frameworks they prefer to pursue certification/accreditation processes in alignment with the set national standards.

PART B: COMMENTS ON THE BILL

No.	CLAUSE	PROPOSED AMENDMENT/INCLUSION	RATIONALE AND JUSTIFICATION
1.	**Part 1- Preliminary** **Interpretation**	**Consider the following inclusion: -** "Patient safety" means prevention of harm to patients during the process of healthcare delivery. It focuses on minimizing risks, errors, and adverse events that could result from medical care rather than	• Clear interpretation of terms provides precision and consistency avoiding ambiguity and gives guidance for implementation of laws. • Provides clarity within the meaning of the Act.

		from the patient's underlying condition. It includes but not limited to ensuring accurate diagnoses and treatments, reducing medication errors, preventing infections and surgical complications, creating systems for reporting and learning from mistake.	
2.	**18. Patient Safety and Quality Assurance Measures** 1. A health facility shall— (a) implement measures to ensure patient safety and quality of healthcare in their health facility; (b) provide healthcare services or perform a medical procedure for which the health facility or healthcare provider at the health facility is duly qualified and licensed under this Act or any other relevant laws; and (c) adhere to the scope of practice for the healthcare providers employed or contracted	**Consider the following inclusion: -** (cc) The Cabinet Secretary shall ensure that the scope of practice for all healthcare cadres employed or contracted in health facilities are developed, published, and reviewed at least every three years.	• This will provide practical flexibility and avoids penalizing Health Facilities. Further in instances where the scope of practice is not yet published, facilities may continue the existing duties for these cadres for up to two years as the relevant regulatory authority finalizes and gazettes an official scope.

	in health facilities as prescribed by the Cabinet Secretary.		
3.	**20. Evidence based Practice** (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.	**This clause is amended as follows: -** (2) The Director-General, develop and publish clinical guidelines at least every three years or in response to major public health developments, and shall maintain a publicly accessible repository of current guidelines.	• The stipulation by the Director-General to develop and publish clinical guidelines from time to time is ambiguous and a clear definite time should be set to create consistency in applicable
4.	**21. Safety and Risk Management** (1) Every health facility shall— (a) implement infection prevention surveillance and control measures as prescribed by the Cabinet Secretary; (b) establish systems for the safe use, storage and administration of health products and technologies, integrated to the Comprehensive Integrated Health Information System established under the Digital Health Act;	**Consider the following inclusion: -** **e.** Establish and implement Clinical Risk Management measures as prescribed by the Cabinet Secretary reviewed at least every three years and	• Kenya lacks a harmonized IPC guideline framework; basing requirements on evidence-aligned national standards improves clarity and feasibility. • Infection Prevention Surveillance and Control measures is just an aspect of Clinical Risk Management and therefore narrows the focus Risk Management in Patient Safety.

	(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 (d) implement procedures for detecting, analyzing and reducing health risks and adverse events		
5.	**22. Quality Improvement.** (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.	**This clause is amended as follows: -** Section 23(4) Compliance with quality improvement standards shall inform accreditation and performance assessment. Access to the Social Health Insurance Fund shall be subject to a transparent, phased framework with due process, allowing facilities to align progressively with quality improvement benchmarks. **Consider the following inclusion:**	• Compliance should be deemed as contribution but it should not be the sole basis for SHA accreditation.

		4a) The Authority shall collaborate with existing bodies such as Kenya Accreditation Service for purposes of ascertaining technical competence.	
6.	**23. Training and Competency** Every county government and health facility shall— (a) verify the qualifications and licensure of healthcare providers before employment; and (b) provide periodic training on patient safety, clinical guidelines and quality improvement	**This clause is amended as follows: -** (a) verify qualifications and active licensure, where such licensure exists, from the relevant regulatory body. For healthcare providers not yet formally licensed, county governments shall maintain verified competency records and submit them annually to the Authority for review	• Given the expanded definition of healthcare providers in in Part I (2) of this bill that includes up to community health workers, options should be provided for health workers without regulatory bodies.
7.	**24. Professional Indemnity** (1) Every health facility shall maintain a valid professional indemnity cover to protect the health facility against claims arising from acts or omissions	**This clause is amended as follows: -** 1) Every health facility shall maintain professional	• This is the first-time indemnity is made mandatory. While globally aligned, it could raise compliance costs and lead to

	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.	indemnity cover appropriate to its level of risk, as prescribed by the Cabinet Secretary in consultation with sector stakeholders **Consider the following inclusion: -** **2C)** The Authority shall phase in individual professional indemnity for healthcare providers based on cadre, risk exposure, and ability to pay, and may coordinate subsidized schemes	risk-averse behavior or doctor attrition without support mechanisms. • Mandatory professional indemnity should be phased in with guidance from respective regulators and tied to facility size and service complexity
8.	**27. Functions of the Authority** 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;	**This clause is amended as follows: -** **By deleting the words license and accredit in paragraph b.** The functions of the Authority shall be to—	• Functions of the Authority should be streamlined to give sufficient attention to quality of care and patient safety while avoiding duplication with councils. Inspection, accreditation, and policy oversight should involve co-

	(d) enforce compliance with quality of healthcare standards (e) inspect health facilities for compliance with quality of 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 of healthcare; (h) accredit health facilities for purposes of empanelment and contracting under section 33 and 34 of the Social Health Insurance Act; (i) maintain a register of registered, licensed and accredited health facilities (j) inspect and accredit health facilities for purposes of internship and training. (k) Promote public awareness on quality of healthcare including patient rights (l) Build capacity on matters related to quality of	(a) regulate the development of health (b) register health facilities; (c) regulate the conduct of health facilities; (d) inspect health facilities for compliance with quality of healthcare standards; or allow for Sub contraction of independent entities, whereas the authority provides oversight **(e)** undertake or cause to be undertaken, regular inspections, monitoring and evaluation of health facilities to ensure compliance with the provisions of this Act; (f) establish and implement a system of accreditation of health facilities for quality of healthcare; (g) enforce compliance with quality of healthcare standards;	regulation with councils under a statutory Joint Regulatory Coordination Committee. • Accreditation should be done by an independent body such as KENAS • An equalization framework needs to be established by the authority for recognition of other certification frameworks and international standards aligned to KQMH framework.

	healthcare (m) Provide policy advise and make recommendations to the Cabinet Secretary on matters related to quality of healthcare (n) advise the cabinet secretary and county governments on the standards of quality of healthcare for health facilities and (o) perform such other functions as may be prescribed by any other written law or as necessary for the promotion of the objects of this Act.	(h) promote public awareness on quality of healthcare including on patient rights; **(i)** maintain a register of registered, licensed and accredited health facilities, **(j)** build capacity on matters related to quality of healthcare; (k) provide policy advice and make recommendations to the Cabinet Secretary on matters related to quality of healthcare; and (l) advise the Cabinet Secretary and county governments on the standards of quality of healthcare for health facilities; **(m)** perform such other functions as may be prescribed by any other written law or as necessary for the promotion of the objects of this Act.	

9.	**29. Board of Directors of the Authority.** (1) The management of the Authority shall vest in a Board of Directors consisting of— a) a chairperson appointed by the president. b) the principal Secretary in the ministry for the time being responsible for matters relating to quality of healthcare standards or a representative designated in writing; c) the principal secretary for the National Treasury or a representative designated in writing; d) the 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. g) one person appointed by the Cabinet Secretary, not being a public officer, to represent healthcare	**This clause is amended as follows: -** **g)** An individual appointed by the cabinet Secretary not being public officers, nominated by I. Private sector II. Patient's association in Kenya; III. Consortium of health care providers.	• The inclusion broadens the level of representation and enhances more accountability and informed decision making as well as balanced interests. • Further the stakeholder representation should be ratified by their respective groups, not merely nominated and appointed by the Cabinet Secretary. • The Appointments should be subject to public vetting or parliamentary approval for transparency.

	providers; h) one person appointed by the Cabinet Secretary to represent the public		
10.	**49. Application for a license** 1.) 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 a digital health solution that has been certified by the health Agency to be used by the health facility; and g) Any other requirement as may be determined by the Authority	We propose the deletion of (f) because it may not apply to all medical facilities.	• Clause 49 outlines crucial mandatory documents that are required during application of a licence. However, the requirement of (g) should not be mandatory. • Prescribe the medical facilities that be applicable with specifics to their level of operations.

11.	**56. Accreditation of Facilities** The Authority shall, for purposes of ensuring quality of healthcare, accredit health facilities.	We propose the deletion of clause 56,57 and 58	• Registration, Licensing, accreditation and practice oversight of health facilities is rightly placed away from the professional regulatory bodies which has always brought fractured oversight of quality of care in the facilities.
12.	**62. Renewal of accreditation** (1) 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.	**This clause is amended as follows by inserting a new paragraph** **62** (2) Once the health facility has fulfilled all reaccreditation application requirements, the authority shall issue a provisional accreditation for another 90 days.	• This will be a recourse for health facilities in instances where there is delay from the Authority in issuance of the accreditation or inaction due to technical hitches.
13.	**67. Award of a performance rating.** (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	**This clause is amended as follows: -** b) used to determine eligibility for transparent, performance-based incentives as defined in	• Safeguards against misuse or politicization, promotes equity across public and private facilities, enforces regulatory clarity, and minimizes the risk of manipulation.

	be— (a) assigned based on the results of the assessment for quality of healthcare; and (b) used to determine the incentives to a health facility.	regulations, provided that such incentives are structured to avoid penalizing low-resource or underserved facilities and include a clear appeals process	
14.	**79. Enforcement.** (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.	**This clause is amended as follows: -** **a)** Order the temporary suspension of the healthcare service or health facility only in cases of imminent risk to patient safety or serious legal violation, and shall issue a written suspension notice within 24 hours outlining reasons and appeal options, with due regard to continuity of patient care	• Prevents arbitrary or disproportionate action; protects business continuity and patient safety; aligns with Article 47 of the Constitution on fair administrative action.

15.	**80. Oversight role by the Authority** (1) Upon receipt of an inspection report under section 80 (3), the Authority shall— (a) where the report is accompanied by objections, review the objections issue such orders as may be necessary; (b) ensure that relevant measures have been taken against the persons contravening the provisions of the Act. (c) adopt the immediate remedial measures as recommended by the inspector; (d) enforce the temporary closure of the health facility; or (e) impose a penalty as the Board may prescribe. (2) The person subject to enforcement action shall take the necessary measures to— (a) remedy compliance as directed by the Authority or as soon as practically possible; and (b) prevent recurrence. (3) The Authority may, where the case presents an	**This clause is amended as follows: -** by inserting the following new paragraph immediately after paragraph (a) — aa) Subject to (a) where the objection is valid, the facility shall be given at least 14 days to be heard or provide further documentation in support of the objection and an internal review process instituted to necessitate the proportionality of the proposed action. **Consider the following inclusion: -** **2c** A review by a designated quality assurance panel within the Authority, which includes representation from professional councils and private sector stakeholders, has confirmed the	• Prevents arbitrary closure or penalties. Establishes clear, fair, reviewable procedure especially important for private sector viability and legal compliance. • Ensures decisions are proportionate and include technical and sectoral input; prevents arbitrary or overly punitive actions; safeguards professional autonomy. • The right to be heard should be applied on a case by case basis and shouldn't be abused in instances where patients right have been outrightly been prejudiced.

	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.	necessity and proportionality of the proposed action.	

Additional Comments: Global lessons & Best Practice

To help develop the best practice for the QOC Bill of Kenya, it is important to first reflect on the use of standards, licensing, quality improvement and accreditation in health systems. Use of regulations and standards is one strategy for improving quality of patient care provided in both the public and private sector. It is important that the same rules and regulations apply for the public and the private sector, especially in Kenya where over 50% of healthcare provision comes from the private sector, addressing healthcare needs from all layers of society.

Common statutory regulatory processes include licensing, certification and accreditation. However, a mechanical approach to "quality control" and inspection of inputs and processes results in static compliance with minimum standards, without stimulating human behavior towards a conscious dynamic improvement, often resulting in blame, punishment and ill-motivated staff and managers.

To be effective, most countries are following these principles when it comes to regulating and incentivizing improvement of quality of care:

- Governmental accreditation programs should not be designed as an extension of governmental "licensing" systems. Instead, accreditation of health provider institutions that comply with standards for safe and reliable care should be undertaken by a government-approved, but independent & legal third-party institution(s) that represents the interests of ministry of health, insurers, providers and patients. Healthcare providers should be able to choose an accreditation body that fits their mission, purpose and client base.
- Inspection carried out to assess whether health provider institutions comply with minimum conditions for licensing and standards for patient safety, including determining whether healthcare professionals providing those services meet the required minimum educational qualifications and credentials, should be separate from determining whether the health professionals are maximizing their training and skills through lifelong

learning. The former is the role of an independent body of the ministry with a legal mandate, while the latter is the role of professional regulatory bodies which also must deal with indiscipline and malpractice within the profession. Often, inspection of health provider institutions is undertaken by medical professional councils for doctors, nurses and laboratory technicians. This could result in confusion and duplication of efforts.

Health professional training and practice standards contribute to healthcare quality and safety. Licensing is very helpful when the health care market does not adequately guard against under-qualified professionals. Licensing provides a legal underpinning for malpractice and while it provides a means to remove fraudulent or incompetent health care providers from practice, it is not enough. Therefore, in addition, re-certification is needed to ensure health care providers remain up-to-date in their knowledge and practice within the continually evolving evidence-based medicine. Licensing and re-certification by a nationwide professional body might save time and money for employers by providing a short cut to confirm that a candidate for a job meets basic qualifications.

Within the Kenyan context, regulatory reforms should ideally target five key aspects that include: the health workers, the public and private health institutions, the quality and availability of essential medical supplies and reform of public and private insurance. Moreover, and to be effective, the three regulatory processes, namely licensing, certification and accreditation, should be designed as 'separate' programmes with different objectives, incentives/ disincentives, staff and reporting structure.

1. Case Studies

Case study – Ghana

In Ghana the Health Facilities Regulatory Agency (HeFRA) Ghana's legal licensing for healthcare facilities. Professional licensing is governed by respective councils— Medical and Dental Council, Nurses and Midwifery Council and Allied Health Council. Accreditation entities, including COHSASA, offer high-level accreditation; SafeCare provides a structured, stepwise improvement path, widely used in Ghana and now incorporated into regulatory practices.

Licensing structure:

Health Facilities Regulatory Agency (HeFRA)

Established under the Health Institutions and Facilities Act, 2011 (Act 829), HeFRA is the statutory body responsible for categorizing, registering, inspecting, licensing and monitoring, all public and private healthcare facilities in Ghana. The HeFRA licensing is considered the fundamental process for assuring quality in healthcare facilities in Ghana by ensuring the basic requirement of staffing, equipment, infrastructure and facilities, etc. are in place for the services to be rendered. The licenses of facilities are renewed periodically (1 – 3 years) depending on the type of facility.

Process overview:

- Registration: Facilities apply via HeFRA's website or offices
- Inspection: HeFRA assesses facility readiness.
- Licensing: A license is issued if standards are met.
- Monitoring: Ongoing inspections ensure compliance.

Professional Councils & Accreditation Bodies

These Councils regulate and license the healthcare professionals, with licenses that are renewable annually through the required scores from continuous professional development CPD programs.

- Medical and Dental Council (MDC) regulates training and practice standards for doctors and dentists.
- Nurses and Midwifery Council (N&MC) regulates nursing and midwifery, including examinations and licensing—established under the Health Professions Regulatory Bodies Act, 2013 (Act 857).
- Allied Health Professions Council oversees training, accreditation, licensing, and regulation of allied health professionals, also under Act 857.

National Health Insurance Authority - Credentialing

The Authority employs credentialing processes to verify the licenses, qualifications, experience, and competence of the healthcare providers to deliver safe and effective care. It is the processes through which the Authority determines which facilities are allowed to be empaneled in an insurance scheme, to receive subscribers. The outcome of the credentialing process determines the facility's tariff assigned, and credentialing is renewed every two years.

COHSASA (Council for Health Service Accreditation of Southern Africa)

A not-for-profit accreditation body founded in South Africa in the mid-1990s. It offers accreditation programs for a wide range of healthcare facility types—from clinics to tertiary hospitals—and is internationally accredited by ISQua.

SafeCare

Established in 2011, SafeCare is a stepwise quality improvement and certification system, created by a partnership of COHSASA, PharmAccess (Netherlands), and Joint Commission International. Designed for low-resource settings, SafeCare provides a graded approach—facilities earn "Certificates of Improvement" from Level 1 (basic) to Level 5 (advanced). Achieving Level 5 can prepare facilities for full accreditation by COHSASA or JCI.

Case study in the Netherlands:

Healthcare Accreditation and Licensing Structure in The Netherlands

In the Netherlands, healthcare accreditation and licensing operate within a tightly regulated framework to ensure high-quality care, patient safety, and professional accountability. The system is overseen by the Ministry of Health, Welfare and Sport (VWS), in collaboration with independent regulatory and professional bodies.

Licensing Structure

1. **Institutional Licensing**
   Healthcare institutions must be licensed under the Healthcare Institutions Admission Act. This allows them to legally operate and receive funding under the Dutch Health Insurance Act.

2. **Professional Licensing**
   Healthcare professionals are licensed through the **BIG-register**, under the **BIG Act**. This register ensures that professionals (e.g., doctors, nurses, pharmacists) meet the required educational and ethical standards to practice.

Accreditation Structure

1. **Institutional Accreditation**
   Accreditation of healthcare institutions is **voluntary** but widely adopted to ensure and demonstrate quality improvement. Dutch organizations such as the **Nederlands Instituut voor Accreditatie in de Zorg (NIAZ)** offer assessments based on internationally recognized (Isqua) standards.

2. **Professional Accreditation and Revalidation**
   Healthcare professionals maintain their BIG registration through **Continuous Professional Development (CPD)**, revalidation, and in some cases, participation in professional peer review and audit systems.

Role of International Accreditation Bodies in the Netherlands

International accreditation bodies like **Joint Commission International (JCI)** and **ISQua** (International Society for Quality in Health Care) play an important influential role by:

- **Providing globally recognized quality benchmarks** for Dutch hospitals that serve international patients or seek international reputation.
- **Enhancing internal quality systems** through external peer-reviewed audits aligned with global best practices.
- Supporting harmonization with **European and international healthcare standards**, which is particularly relevant for cross-border care and international collaboration.

- Acting as reference points for **Dutch national accrediting bodies** (e.g., NIAZ), many of which align their methodologies with ISQua principles for broader credibility.

Interplay Between Licensing and Accreditation

- **Licensing is mandatory** and ensures legal and professional compliance, while **accreditation is voluntary** and focused on continuous improvement.
- Accreditation can positively influence institutional reputation, patient trust, and even financial contracts with insurers.

In summary, the Dutch system integrates **mandatory licensing** with **voluntary national and international accreditation**, forming a robust framework for quality assurance, professional accountability, and international alignment in healthcare delivery. Healthcare providers may choose an accreditation body that meets that purpose. This can be local body NIAZ, but also international body JCI. Large hospitals that cater to international patients tend to prefer JCI accreditation, whereas smaller regional hospitals choose the Dutch accreditation body NIAZ.

Case study in the US

Each U.S. state mandates healthcare facilities operating within its jurisdiction to obtain and maintain a license. State licensure laws typically govern:

State departments of health are responsible for inspecting facilities for compliance with these laws, often through their own surveyors or third-party contractors. These inspections may occur every 1 to 3 years, depending on state policy and facility type (e.g., hospitals, ambulatory surgery centers, long-term care).

Although accreditation and licensure are distinct, there is substantial overlap in the domains they assess. Many states have moved toward recognizing national accreditation by organizations like the Joint Commission (and by extension, JCI standards in aligned global facilities) as a proxy for part or all of state inspection requirements. This process, known as "deemed status," reflects:

- **Reduced duplication:** If a hospital is accredited by a recognized body, states may waive some or all inspection requirements.
- **Standard harmonization:** States align their regulatory expectations with those developed by private accreditation bodies.

For instance:

- **California and New York** accept Joint Commission accreditation for hospital licensure compliance but retain authority to inspect under specific complaints or adverse events.
- **Texas and Florida** perform risk-based inspections, placing less frequent scrutiny on accredited hospitals.

Case study in Thailand

Healthcare Accreditation and Licensing Structure in Thailand

As of 2019, Thailand's population of 68 million is served by 927 government hospitals and 363 private hospitals with 9,768 primary care health units (SHPH clinics), responsible for Thai citizens' health at the sub-district level.

Universal health care is provided through three programs: the civil service welfare system for civil servants and their families, Social Security for private employees, and the universal coverage scheme, introduced in 2002, which is available to all other Thai nationals. Some private hospitals are participants in the programs, but most are financed by patient self-payment and private insurance. According to the World Bank, under Thailand's health schemes, 99.5 percent of the population have health protection coverage.

Thailand has a multi-layered healthcare licensing and accreditation structure, combining mandatory government licensing under the Medical Facility Act with voluntary national and international accreditation programs. The Healthcare Accreditation Institute (HAI) runs the national Hospital Accreditation (HA) program, while international bodies like Joint Commission International (JCI) provide global certification. Facilities must also adhere to regulations from the Thai Food and Drug Administration (TFDA) for product and service quality.

Licensing Structure

Licensing for healthcare organizations is mandatory.

This act requires hospitals to obtain two types of licenses to operate:

- a license to operate a medical facility, granted to the facility owner for 10 years and:
- a license to manage a medical facility granted to the supervising medical professional for two years.

Accreditation Structure

Accreditation for healthcare institutions is voluntary.

- **The Healthcare Accreditation Institute (HAI)** develops and implements standards to assess and certify the quality of healthcare facilities nationwide.

The Healthcare Accreditation Institute (HAI) is a public organization responsible for quality improvement and accreditation of healthcare organizations in Thailand. The status as a government agency enhances the credibility of the Institute and provides HAI getting some budget support from the government. The institute has been accredited by an international organization, The International Society for Quality in Health Care External Evaluation Association (IEEA).

Role of International Accreditation Bodies in the Thailand

- Many Thai hospitals voluntarily seek accreditation from international bodies like Joint Commission International (JCI).
- JCI accreditation is considered a global "gold standard" for quality and patient safety standards.
- Thailand has a high number of JCI-accredited hospitals, particularly in the private sector.
- As of February 2025, there are 63 Joint Commission International (JCI)-accredited medical institutes in Thailand, making it a leading country in the Asia-Pacific region for high-quality, internationally recognized healthcare facilities. These accreditations highlight the Thai healthcare sector's commitment to patient safety and quality of care, which has helped establish Thailand as a top destination for medical tourism.

Interplay Between Licensing and Accreditation

In summary, the Thai system integrates **mandatory licensing** with **voluntary national and international accreditation**, forming a robust framework for quality assurance, professional accountability, and international alignment in healthcare delivery.

Kenya now has the opportunity to move beyond minimum compliance and punitive inspections, and instead build a reformed regulatory framework where licensing, certification, and independent accreditation serve as complementary pillars. Anchored on clear roles and accountability, this framework will transform the Quality Healthcare and Patient Safety Bill from a compliance exercise into a powerful driver of continuous improvement, patient safety, public trust, and universal health coverage in Kenya.

2nd Floor, Kedong House, Lenana Road/Ralph Bunche Road
ction

Meet the Kenya Healthcare Federation members - Health Organizations (1/3)

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ction

Meet the Kenya Healthcare Federation members - Health Organizations (2/3)

Meet the Kenya Healthcare Federation members -(3/3)

Institutional / Trade Associations

FKPM
HENNET
KAH KENYA ASSOCIATION OF HOSPITALS
MEDAK
MIPAK
TOGETHER FOR BETTER
HPA
KAPI KENYA ASSOCIATION OF PHARMACEUTICAL INDUSTRY
Sightsavers
kaph

Health Professionals Associations

KVA
Kenya Dental KDA Association
KENYA PAEDIATRIC ASSOCIATION
KACP
Kenya Health Professionals Society
PHARMACEUTICAL SOCIETY OF KENYA
ReSOK RESPIRATORY SOCIETY OF KENYA

(2) Mr Abdi Hassan Dead 9/9/25

(1) DP C Please deal. 08/09/25

KENYA NATIONAL COMMISSION ON HUMAN RIGHTS

MEMORANDUM ON

THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

SUBMITTED TO

CLERK OF THE NATIONAL ASSEMBLY

DATED: 5TH SEPTEMBER 2025

Kenya National Commission on Human Rights
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NATIONAL ASSEMBLY
RECEIVED
08 SEP 2025
CLERK'S OFFICE
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NATIONAL ASSEMBLY
RECEIVED
08 SEP 2025
DEPUTY CLERK, S. KIOKO
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DIRECTORATE OF DEPARTMENTAL COMMITTEES
RECEIVED
08 SEP 2025

A. INTRODUCTION

1. The Kenya National Commission on Human Rights ("KNCHR" or "National Commission") is an independent National Human Rights Institution established under **Article 59** of the Constitution with a broad mandate to promote a culture of respect for human rights in the Republic of Kenya. The operations of the National Human Rights Commission are guided by the KNCHR Act and the United Nations *Paris Principles* on the establishment and functioning of independent national human rights institutions commonly referred to as the Paris Principles and as such enjoys an "A" status accreditation.

2. The National Commission under **Article 249** of the Constitution has a mandate to secure observance of all state organs of democratic values and principles and to promote constitutionalism. **Article 10** of the Constitution requires all state organs to uphold constitutionalism and the rule of law whenever they make public policy decisions or interpret the Constitution. One of the strategies pursued by the Commission to secure observance of all state organs of democratic values and principles is through human rights monitoring, review of new and existing laws and policies, and the issuance of advisories informed by the KNCHR's analysis.

3. In this regard, the KNCHR submits its comments on the **Quality Healthcare and Patient Safety Bill, 2025** 2025, sponsored by the Hon. Kimani Ichung'wah, Leader of the Majority Party. The advisory has three parts; Section A covers preliminary introduction, Section B provides General observations and recommendations, while specific comments/observations on particular clauses of the Bill are detailed in Section C.

B. GENERAL COMMENTS

4. The Commission welcomes the provisions of the Bill seeking to give effect to Article 43 (1) of the Constitution; to provide for the responsibility of the national and county governments in the realisation of quality of healthcare for patients; to provide for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, registration, licensing and accreditation of health facilities; to provide for the setting of standards for quality of healthcare; among others.
5. The Commission notes that the objects and the guiding principles of the proposed legislation lay the basis for ensuring that health facilities provide healthcare services in a manner that guarantees high quality care, safety, effectiveness and efficiency, which the Commission proposes that the Bill be amended to refer to and guarantee the highest attainable standards of healthcare by ensuring that healthcare services provided by both public and private health facilities meet the **availability, accessibility, acceptability and quality (AAAQ) framework** under General Comment No. 14 on the Right to the Highest Attainable Standard of Health developed by the Committee on Economic, Social and Cultural Rights.

6. The rights-based and patient-centred care under Part II of the Bill is welcome. The specific rights include the right to safe and accessible health facilities (clause 8); right to care by a qualified health professional (clause 9); right to information and decision-making (clause 10); right to safe and quality care (clause 11); right to timely and effective care (clause 12); right to safe processes and practices (clause 13); right to safe and quality health products and technologies (clause 14); right to dignity and equity (clause 15); right to be heard (clause 16). The Commission however notes the need to expressly provide for the right to maternal care following the Court of Appeal decision in ***County Government of Bungoma & 2 others v. Josephine Oundo Ongwen (AKA Josephine Majani) & 2 Others*** that there is a **minimum core threshold** to the right to health that **must be realized immediately** and is **not subject to progressive realization.**
7. The right to emergency medical treatment is Constitutionally guaranteed under Article 43 (2) and further provided under Section 7 of the Health Act, Cap. 241. While the Bill has defined emergency medical treatment, the Commission notes the need to provide categorically that health facilities shall not demand for prepayment of prospective medical costs as a condition for the provision of emergency medical treatment. This is important to ensure the realization of the right to emergency medical treatment and overall quality and health outcomes for patients as provided in the Bill, noting that facilities have the tendency of demanding payments upfront.
8. The Bill also seeks to ensure patients access quality healthcare services that are safe and dignified. The Commission holds the view that the concept of patient dignity ought to be expanded by restraining health facilities from withholding or detaining the body of a deceased patient for purposes of enforcing settlement of pending medical bills. The High Court in ***Mary Nyang'anyi Nyaigero & another v Karen Hospital Limited & another [2016] KEHC 6882 (KLR)*** held that hospital bills are civil debts which can lawfully be recovered by following the civil process not by detaining a body that has no monetary value.
9. The Commission notes that whereas the Bill seeks to amalgamate the role of registration, licencing, accreditation and inspection of health facilities to safeguard and ensure quality standards of care, there will be need for close collaboration between the Authority and regulatory bodies in place. Further, the inspectors that will be engaged by the Authority must possess relevant professional expertise for the health facilities they are to assess.
10. The Commission also welcomes the requirement to the effect that compliance to quality improvement standards shall form the basis for health facility accreditation, performance assessment and access to the Social Health Insurance Fund. This ensures that facilities must undergo periodic reviews and submit information to the Authority to demonstrate that they meet prescribed quality standards to bill SHA for health insurance services.

C. SPECIFIC COMMENTS

No.	Clause & Title	Proposed Amendment	Rationale
1.	Clause 2-Interpretation	The Commission proposes that the Clause be amended by introducing definition of the following terms: • Quality improvement • Quality assessment	For clarity and to help avoid ambiguity in their interpretation and application.
2.	Clause 3- Objects of the Act	Clause 3 (d) of the Bill provides that one of the objects of the Act shall be to **ensure health facilities provide healthcare services in a manner that guarantees high quality care, safety, effectiveness and efficiency.** The Commission proposes that the Clause be amended to read as follows: *3 (b) ensure health facilities provide healthcare services in a manner that guarantees availability, accessibility, acceptability and quality.*	To align with the "**Availability, Accessibility, Acceptability, Quality" (AAAQ) framework** under General Comment No. 14 on the Right to the Highest Attainable Standard of Health developed by the Committee on Economic, Social and Cultural Rights[1] based on article 12 of the International Covenant on Economic, Social and Cultural Rights which Kenya is a signatory. The Commission contends that as the Bill seeks to give effect to Article 43 (1)(a), the right to health in all its forms and at all levels must cover the interrelated and essential elements, and applied in accordance to the AAAQ framework expounded as follows: • Availability- guaranteeing that functioning public health and health-care facilities, goods and services, as well as programmes, are available in sufficient quantity. This includes other determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings, trained medical personnel and essential drugs;

[1] General Comment No. 14 by the Committee on Economic, Social and Cultural Rights available at https://docs.un.org/en/E/C.12/2000/4

No.	Clause & Title	Proposed Amendment	Rationale
			• Accessibility- guaranteeing that health facilities, goods and services have to be accessible to everyone without discrimination. This includes overlapping dimensions such as ***physical accessibility*** where health facilities, goods and services are to be within safe physical reach for all sections of the population; ***economic accessibility*** (affordability) of health facilities, goods and services must be affordable for all; and ***information accessibility*** regarding the right to seek, receive and impart information and ideas concerning health issues to all persons seeking healthcare services including *persons with disabilities*. • Acceptability- guaranteeing that all health facilities, goods and services are respectful of medical ethics and culturally appropriate to individuals, minorities and communities, as well as being designed to respect confidentiality and improve the health status of those concerned. • Quality- guaranteeing that aside from being culturally acceptable, health facilities, goods and services must also be *scientifically and medically appropriate and of good quality*. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate hospital sanitation.
3.	Clause 8- Right to safe and accessible health facilities	Clause 8 (2) (c) mandates health facilities to **provide reasonable modifications to enable accessibility by persons with special needs;** The Commission recommends that Clause 8(2)(c) be amended to read as follows:	To expand the mandate of health facilities beyond physical accessibility to the broader component of reasonable accommodation. Section 2 of the Persons with Disabilities Act, 2025 defines reasonable accommodation as necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with

No.	Clause & Title	Proposed Amendment	Rationale
		8(2)(c) provide reasonable accommodation to patients with disabilities;	disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms. The Commission notes that health facilities should be mandated to provide reasonable accommodation to cover aspects such as sign language interpreters, offering large print or braille materials health information products/information, ensuring physical accessibility of equipment like accessible exam tables and ramps among others. These holistic accommodations over and above physical accessibility would ensure patients with disabilities receive healthcare on an equal basis with others as provided under Section 24 of the Persons with Disabilities Act, 2025.
4.	Clause 15-Right to dignity and equity	The Commission recommends that Clause 15 (2)(b) be amended to cover all the discriminatory grounds provided under Article 27 (4) of the Constitution so as to read as follows: *15 (2)(b) non-discriminatory treatment regardless of race, sex, pregnancy, marital status, health status, ethnic or social origin, colour, age, disability, religion, conscience, belief, culture, dress, language or birth.*	To align with Article 27 (4) of the Constitution.
5.	New clause- Right to maternal care	The Commission proposes introduction of **a new clause to provide for the right to maternal care**, with the following rights: i. The right to be free from physical violence and verbal abuse during labour and childbirth; ii. The right to be free from discrimination during labour and childbirth;	To implement the Court of Appeal decision in *County Government of Bungoma & 2 others v. Josephine Oundo Ongwen (AKA Josephine Majani) & 2 Others* where the Court deployed **the minimum core threshold** to the right to health that **must be realized immediately** and is **not subject to progressive realization,** thereby framing the proposed rights to constitute the minimum core of a woman's right to respectful maternal care during child birth.

No.	Clause & Title	Proposed Amendment	Rationale
		iii. The right to a dignified and respectful care – including being granted acceptable levels of privacy and confidentiality during labour and childbirth.	It is important to promulgate this landmark Court decision through the proposed Bill as it seeks to guarantee the quality of care and overall best health outcomes for all patients as a positive step towards a human rights-based maternity care, where dignified and respectful care experiences for women during childbirth, free from violence and discrimination should be the new norm.
6.	29- Board of Directors of the Authority	Clause 29 (2) of the Bill provides that the appointment of the chairperson and members under subsection (1)(e), (f) and (g) shall be by notice in the *Gazette*. The Commission proposes that the clause be amended as follows: *29 (2) The appointment under this section shall be by notice in the Gazette.*	It is good governance practice to provide for the gazettement of all the members of the Board of Directors of the Authority and not just a segment as currently proposed. This is critical in formalizing their legal standing and pave way for commencement of official duties under the proposed legislation.
7.	Clause 46-Suspension of the certificate of registration Clause 47 -Revocation	The Commission proposes that clauses 46 and 47 be amended by introducing a new paragraph to mandate the Authority to adhere to Fair Administrative Action Act, Cap. 7L in when considering suspension or revocation of certificate of registration of health facilities.	To align with the provisions of the Fair Administrative Action Act, Cap. 7L.
8.	Clause 46-Suspension of the certificate of registration	The Commission proposes introduction of a new clause 46 (5) as follows:	To officially notify the public through a notice in the Gazette regarding information on health facilities whose certificates of registration suspended or reinstated. This is crucial in safeguarding the quality of healthcare and patient safety.

No.	Clause & Title	Proposed Amendment	Rationale
		46. (5) The Authority shall Gazette the details of a health facility whose certificate of registration has been suspended or reinstated.	This is also in taking cue from clause 47 (4) which provides fo Gazettement of details of health facilities whose certificate o registration has been revoked.
9.	Clause 53- Services offered by health facilities.	The Commission proposes that Clause 53 be amended by introducing a new sub-clause immediately after clause 53 (2) to read as below and renumber the clauses accordingly: *53 (3). Health facilities shall not demand for prepayment of prospective medical costs as a condition for the provision of emergency medical treatment.*	Article 43 (2) of the Constitution provides that a person shall not b denied emergency medical treatment and this is also guaranteed unde Section 7 of the Health Act, Cap. 241. The Commission notes that the proposed legislation already define emergency medical treatment and guarantees quality of health care ir a way that ensures healthcare services are safe, effective, timely efficient, equitable, and people centered, provided to an individual that improves health outcomes based on evidence-based standards. Thus, the Commission contends that in order to achieve **patient safety, quality of care and desirable health outcomes as provided in the Bill,** health facilities are to be mandated to respect and ensure realization of the right to emergency medical treatment under Article 43 (2) in the first instance.
10.	Clause 55- Revocation of a licence	The Commission proposes introduction of a new clause 55 (6) as follows: *55. (6) The Authority shall Gazette the details of a health facility whose licence has been revoked.*	As above
11.	Clause 65- Quality improvement in a health facility	The Commission proposes that a new paragraph be introduced immediately before paragraph (a) to read as below and reorganize the numbering correctly: *65. (a) designate a quality improvement team with clear terms of reference;*	A dedicated quality improvement team will enhance accountability and compliance to the proposed quality improvement programs under clause 22 (2) relating service gaps, prioritizing maternal healthcare, primary healthcare, mental healthcare and emergency medical treatment among others. This will also be in line with Ministry of Health's Kenya Quality Model for Health.[2]

[2] Ministry of Health's Kenya Quality Model for Health available at https://qualityhealthcareawards.com/wp-content/uploads/2020/01/KQMH-Hospital-Checklist-for-assessing-Quality-of-Care.pdf

No.	Clause & Title	Proposed Amendment	Rationale
12.	Clause 67-Award of a performance rating	The Commission proposes that a new paragraph be introduced under clause 67 to provide for the timeline within which the Authority is required to undertake quality assessment of a health facility and award of a performance rating.	Provision for a timeline enhances predictability and sustainability of quality improvement programs by health facilities as well as mandating the Authority to act on the health facilities' self-assessment reports by way of performance scoring within timelines to be stipulated. This ensures overall compliance on quality improvements by both health facilities and the Authority. This will also be in accordance with Clause 70 (3)(h) which makes it mandatory for the register of registered, licenced and accredited health facilities to contain information quality rating and scores.
13.	Clause 75-Qualifications of inspectors	The Commission proposes that clause 75 be deleted.	For legislative harmony and to avoid duplication since the provision in Clause 75 has already been made under Clause 72 (1).
14.	Clause 83-Establishment of the Health Care Tribunal.	The Commission recommends that Clause 83 (4) be amended to cap the number of Health Care Tribunal member to not more than seven (7).	To make the Tribunal effective and efficient in the discharge of its functions. The Commission also wishes to point out that Tribunals established under existing legislation frameworks highlighted below have set a maximum of seven (7) members for a Tribunal hence the need to align the clause on Tribunal membership in the proposed Bill to the existing frameworks. • The Education Appeals Tribunal- 7 members • The Political Parties Disputes Tribunal- 7 members • The HIV and AIDS Tribunal- 7 members • The Micro and Small Enterprises Tribunal- 6 members • The National Civil Aviation Administrative Review Tribunal- 6 members • The Competition Tribunal- 5 members
		The Commission proposes that clause 83 (7) be amended by replacing the words ***"Cabinet Secretary"***	The Court of Appeal in Attorney General v Okoiti & 3 others [2025] KECA 309 (KLR) affirmed the High Court decision among others, that Tribunals established pursuant to article 169(1)(d) of

No.	Clause & Title	Proposed Amendment	Rationale
		with ***"Judicial Service Commission"*** *to read as follows:* *83 (7). 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.*	the Constitution of Kenya, 2010 are not part of the Executive machinery, nor are they independent adjudicatory bodies, but are subordinate courts which are an integral part of the Judiciary. Further, the Commission notes that the National Assembly Departmental Committee on Justice and Legal Affairs while considering the Tribunals Bill, 2023 (Bill lapsed) observed that since the tribunals are being transited to the Judiciary, the remuneration of the members of the should be determined by the JSC in consultation with SRC.[3]
		The Commission proposes that Clause 83 (8) of the Bill be amended by replacing the words "Cabinet Secretary" with "Chief Justice" so as to read as below: *83 (8). The Chief Justice shall make rules for operationalization of the Tribunal.*	The Court of Appeal in Attorney General v Okoiti & 3 others [2025] KECA 309 (KLR) affirmed the High Court decision, among others, that Tribunals established pursuant to article 169(1)(d) of the Constitution of Kenya, 2010 are not part of the Executive machinery, nor are they independent adjudicatory bodies, but are subordinate courts which are an integral part of the Judiciary. Further, the Commission notes that the National Assembly Departmental Committee on Justice and Legal Affairs while considering the Tribunals Bill, 2023 (Bill lapsed) observed that the Chief Justice should be the one responsible for making rules governing Tribunals.[4]
15.	Clause 97- Offences	The Commission proposes that Clause 97 be amended by introducing further offences as below:	To give effect and ensure realization of the right to emergency medical treatment as provided under Article 43 (2) and section 7 of the Health Act. Cap. 241. The Bill already makes provision for emergency medical treatment as a quality standard hence the

[3] JLAC Report on Tribunals Bill, 2023 available at https://parliament.go.ke/sites/default/files/2025-04/Report%20of%20the%20DC%20on%20Justice%20%26%20legal%20Affairs%20on%20the%20Consideration%20of%20the%20Tribunals%20Bill%2C%20%28National%20Assembly%20Bill%20No.%2045%20of%202023%29.pdf

[4] JLAC Report on Tribunals Bill, 2023 available at https://parliament.go.ke/sites/default/files/2025-04/Report%20of%20the%20DC%20on%20Justice%20%26%20legal%20Affairs%20on%20the%20Consideration%20of%20the%20Tribunals%20Bill%2C%20%28National%20Assembly%20Bill%20No.%2045%20of%202023%29.pdf

No.	Clause & Title	Proposed Amendment	Rationale
		(f) demands or permits the demand of payment of prospective medical fees or admission fees prior to providing emergency medical treatment; *(g) detains or permits the detention of the body of a deceased patient for purposes of enforcing settlement of pending medical bills,*	provision for an offence and corresponding penalty will ensur enforcement and compliance. Further, to expand the concept of patient dignity by restrainin health facilities from withholding or detaining the body of deceased patient for purposes of enforcing settlement of pendin medical bills in accordance with the High Court decision in ***Mar Nyang'anyi Nyaigero & another v Karen Hospital Limited & another [2016] KEHC 6882 (KLR)*** which held that hospital bills are civil debts which can lawfully be recovered by following the civil process not by detaining a body that has no monetary value.
16.	Second Schedule (s. 101)-Consequential Amendments to other Acts Amendment of section 112 of Cap. 241.	Clause 101 (10) seeks to amend Section 112 of the Health Act is amended by- (a) deleting paragraph (a); (d) deleting paragraph (e); **The Commission proposes that the proposed amendments be dropped.**	The proposed Bill does not provide for the fees to be paid to access services in a public health facility other than fees for registration, licencing and accreditation of health facilities. The Commission notes that deletion of paragraph 10 (a) of Section 112 of the Health Act leaves an incurable lacuna. The Commission further notes that the proposed deletion of paragraph 10 (e) of Section 112 of the Health Act leaves a gap in that the proposed Bill only prescribes that the Authority shall keep a register of registered, licenced and accredited of health facilities and does not extensively cover the nature of returns, registers, reports, records, documents and forms to be completed and kept by health facilities. The Commission is of the view that the two paragraphs should be left intact as is in the Health Act, 2017.
17.	Second Schedule (s. 101)-Consequential Amendments to other Acts Amendment of section 17 of Cap. 253.	Clause 101 (35) seeks to amend the Medical Practitioners and Dentists Act by repealing section 17. **The Commission recommends that the proposed amendment be dropped.**	Section 17 of the Medical Practitioners and Dentists Act, Cap 253 provides a critical safeguard on patient safety and quality of care by ensuring that unregistered practitioners do not purport to offer and charge for services they are not licenced to offer in the first instance.

No.	Clause & Title	Proposed Amendment	Rationale
18.	Second Schedule (s. 101)- Consequential Amendments to other Acts Repeal of Part VIII of No.16 of 2023.	Clause 101 (113) of the Bill proposes to amend the Social Health Insurance Act by repealing PART VIII of the Act. The Commission proposes that Section 43 (1) of the Act be retained to introduce the whole aspect of the Tribunal and to read as below: *43. Health Care Tribunal* *(1) A person aggrieved by a decision made under this Act may, within one month from the date of the decision, appeal to the Health Care Tribunal for a review of such decision.*	Part VIII of the Social Health Insurance Act is essential in introducing and directing aggrieved parties to the Health Care Tribunal established under the proposed Bill. As currently proposed, the total repeal will only result to the Tribunal being referenced in the definition part under section 2 of the Act and nowhere else.

D. CONCLUSION

The Commission acknowledges the Bill for seeking to provide for a rights-based and patient-centred healthcare system through setting of standards for healthcare services and health facilities in a manner that secures the protection, promotion, improvement and maintenance of the health and well-being of every person. The proposed legislation also presents a vital opportunity to transform Kenya's healthcare governance landscape in terms of registration, licencing, accreditation and inspection of health facilities to ensure quality of care, patient safety and rights. The Commission notes that the Authority contemplated in the Bill will need to closely collaborate with relevant regulatory bodies in the performance of its functions. The Commission urges that extensive consultation with sector players should be conducted during the development of regulations contemplated under the Bill for successful implementation of the proposed quality improvement initiatives. Lastly, the Commission calls for full **implementation of the health laws** as well as **adequate budgetary allocation by both the National and County governments** in line with the **Abuja Declaration** to guarantee the realization of the right to the highest attainable standard of healthcare provided under Article 43 of the Constitution.

SIGNED BY:

Dr. Bernard Mogesa, PhD., CPM

Commission Secretary/CEO

② Mr Arale Hassan
Dcad
9/9/25

② DPDC
Please deal
08/09/25

PHARMACEUTICAL SOCIETY OF KENYA

COMMENTS ON THE PROPOSED QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

A. Introduction

The Pharmaceutical Society of Kenya (PSK) is a professional body established in 1964 to advance pharmaceutical practice, promote professional standards, and advocate for pharmacists' welfare. It is registered under the Societies Act, Cap. Cap. 108.

It fosters high standards for medication quality and distribution, promotes pharmacists' role in patient care, and provides opportunities for continuing education and professional development.

The PSK also collaborates with partners, participates in policy formulation, and serves as a vital resource for information exchange within the pharmaceutical community and with the public.

Pursuant to this mandate, the Pharmaceutical Society of Kenya makes the following recommendations to the National Assembly on the Quality Healthcare and Patient Safety Bill, 2025 following a notice of invitation to submit memoranda published on 22nd August, 2025 by the Clerk of the National Assembly in accordance with Article 118 of the Constitution[1].

B. Background

Article 43 of the Constitution provides for social and economic rights which include the right to the highest attainable standard of health including the right to health care services. The health function is devolved, with functions distributed between the National Government and County Governments in the Fourth Schedule. The National Government is tasked with formulation of the Health Policy while the County Governments are assigned the role of managing county health facilities and pharmacies, ambulance services and the promotion of primary health care.

The Health Act, Cap. 241, which seeks to implement the Constitutional provisions on health matters further stipulates that the National Government shall coordinate development of standards for quality health service delivery and promote the use of appropriate health technologies for improving the quality of healthcare.

[1] https://www.parliament.go.ke/matter-consideration-national-assembly-1the-quality-healthcare-and-patient-safety-bill-national.

DIRECTORATE OF DEPARTMENTAL COMMITTEES RECEIVED 08 SEP 2025

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International instruments that Kenya has ratified also speak to this issue and especially in line with health products and technologies and the practice of pharmacy. WHO recognises health products and technologies as one of the key building blocks of a health system. For instance, the WHO's Global Benchmarking Tool (GBT) which defines nine core regulatory functions including licencing of premises and regulatory inspection, requires all medicine-handling facilities of member states (manufacturers, wholesalers and retail pharmacies) to be regulated by **one regulatory body**.

The GBT which classifies national regulatory systems into maturity levels, has classified Kenya at Maturity Level 2 which means Kenya has foundational regulatory structures in place. The aim is to elevate Kenya to ML3 status which means aligning Kenya's ability to independently regulate medical products in line with international good practices.

In line with this, the Pharmacy and Poisons Board in collaboration with the Ministry of Health has made great strides in driving reforms to align the regulatory framework with the WHO standards. This includes establishing quality management systems, digitization of licencing and enhancing post-marketing surveillance.

Attainment of ML3 status for Kenya would be a huge achievement as it would accelerate access to safe and effective medical products through faster approval processes, elevate public trust by ensuring quality and safety in health products and technologies and open up opportunities for mutual recognition arrangements and inclusion into the WHO Listed Authorities networks.

C. Analysis

The Quality Healthcare and Patient Safety Bill, 2025 (the Bill), seeks to create a comprehensive, responsive and structured system for delivering quality healthcare services to all in line with Article 43(1) of the Constitution. The Bill makes provision for patient rights and the responsibility of the National and County Governments in the realization of patient safety and quality healthcare. It provides for the implementation of standards of quality of healthcare and patient safety, for the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority, for registration, licensing and accreditation of health facilities.

The Bill addresses some of the issues and challenges raised in health sector policies. It has made some progressive proposals, for instance, in clause 18 of the Bill, on patient safety and quality assurance measures, it states that every health facility shall adhere to the scope for healthcare providers employed or contracted by them. This aligns with the proposals around the anticipated Pharmacy Practice legislative framework.

However, some suggestions on how to improve the Bill include;-

1. There is need to ensure that, in line with global good practice, regulation of the premises and practice of pharmacists is not separated. This is because the practice is linked to the product held within the premises that is to be dispensed to a patient. Furthermore, Kenya risks losing the ML3 pathway if licencing is split between the Pharmacy and Poisons Board and the proposed Quality Healthcare and Patient Safety Authority.

   In the UK for example, the Medicines and Healthcare Products Regulatory Agency (MHRA), which is the equivalent of the Pharmacy and Poisons Board in Kenya, undertakes the registration and licensing of pharmacies in order to ensure that all pharmacies in the UK are legally compliant and meet standards for the safe handling and provision of medicines. The scope of this regulation entails regulating the pharmacy premises, the medicines they handle, and the sale of medicines, classifying them into legal categories like General Sales List (GSL) and Pharmacy (P). The process involves an initial inspection and approval, followed by applying for staff licensing and a final inspection and fee payment. Afterward, a mandatory licence to operate as a pharmacy is issued.

   National Health Service/Care Quality Commission carries out accreditation whose purpose is to demonstrate a pharmacy's commitment to delivering continuous high-quality patient care, setting high standards, and fostering continuous improvement within the National Health Service. It encompasses various aspects, such as accreditation of specific programmes for staff development or quality assurance of services like hygienic preparation of medicines within National Health Service facilities.

   This involves gathering evidence on whether requirements have been met for roles like training officers and adherence to quality standards, the outcome of which is a voluntary quality benchmark and a route to recognition for practitioners and services within the National Health Service.

2. In line with the above, the PSK urges the Committee to consider recognising Pharmacy as a unique cadre based on how the healthcare service relating to pharmacy is offered across the world. Furthermore, we propose that registration and licencing of community pharmacies is left to the Pharmacy and Poisons Board or to be carried out jointly with the proposed Quality Healthcare and Patient Safety Authority(Authority). This will be integral in safeguarding Kenya's ML3 goal by preserving this integration.

   Borrowing from the UK example, we propose that the Authority retains the role of accreditation of pharmacies in line with the standards and guidelines developed by the Cabinet Secretary and Director-General respectively.

Comments on specific clauses

CLAUSE	COMMENT	JUSTIFICATION
Second Schedule – paragraph 22 and 23A	Consider deleting the two paragraphs which relate to the power of the Pharmacy and Poisons Board to register and close premises.	This is in line with our submission that the registration and licencing of pharmacy premises ought to be a preserve of the Pharmacy and Poisons Board in line with Kenya's ML3 goal.
Second Schedule- Paragraph 25	While this paragraph proposes to delete section 44 of the Pharmacy and Poisons Act which currently gives the Cabinet Secretary responsible for health in consultation with the Pharmacy and Poisons Board the power to make rules on the the standards and practice of pharmacy, the role will still be undertaken by the Cabinet Secretary responsible for health under the Bill. As earlier submitted, the attainment of the ML3	The proposed amendment is not only defective but also in breach of Kenya's commitment to international obligations under WHO.

	status by Kenya is an ongoing process being undertaken by the Ministry in collaboration with the PPB. Consider retaining the current section 44(1)(mb).	

INDUSTRY ALLIANCE OF HEALTH PRODUCTS & TECHNOLOGIES

(2) Arsale Hassan Deal 9/9/25

(1) DDC Please deal. 08/09/25

5th September 2025

NATIONAL ASSEMBLY
RECEIVED
08 SEP 2025
CLERK'S OFFICE
P.O. Box 41842, NAIROBI

To,
The Clerk of the National Assembly,
P.O. Box 41842 – 00100.
Nairobi.

Dear Sir,

RE: KAPI'S POSITION ON THE QUALITY HEALTHCARE & PATIENT SAFETY BILL, 2025.

The KAPI – Industry Alliance of Health Products and Technologies is a membership organization, established in the late 1960s, representing manufacturers (or their local representatives) that through research invent and develop medicines and technologies (e.g., Biopharmaceuticals, Vaccine Healthcare, Medical devices, Diagnostics) that significantly improve people's lives. KAPI presents the industry voice and promotes efficiency in the pharmaceutical industry to ensure that medical products and healthcare technologies of the highest quality can be readily available for diagnosis, prevention, and treatment of diseases. It is in view of this mandate that we are pleased to submit our position on the Quality Healthcare & Patient Safety Bill, 2025, as follows:

Page number and Section	Issue of concern	Proposed changes	Justification
Part II – Patient Rights & Safety, 14 (2)	The original phrasing in the Bill s that "every healthcare provider shall prescribe, administer, and monitor treatment". Is broad and unspecific. It implies that all categories of healthcare providers— including those not legally authorized to prescribe or administer treatment—would be permitted to do so.	Replace the statement "Every healthcare provider shall prescribe, administer, and monitor treatment" with "Every healthcare provider, operating within their authorized scope of practice shall:"	The authority to prescribe, administer, and monitor treatment varies from one healthcare provider to the other and depends on the licensure as issued by the regulatory bodies. The recommended statement ensures that only authorized scopes are permitted.

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Part III – Administration of Quality of Healthcare (29)(1)	Lack of representation of healthcare providers in the composition of the Board of Directors of the Authority.	Healthcare Providers are underrepresented on the Board of Directors of the Authority. Members of the Board should mirror the constitution of other healthcare regulatory authority boards. Refer to the constitution of KMPDC & PPB	A board with strong professional representation can provide informed oversight and advocacy.
Part IV – Registration, licensing and accreditation of health facilities - 42	Deletion of section 42	We propose deletion of section 42. Section 42 outlines the functions of a healthcare authority. Section 42 should be governed by the existing regulatory authority that is - KMPDC, PPB, Nursing Council e.tc	There should not be an overlap of functions with other healthcare regulatory bodies - KMPDC, PPB, Nursing Council, Clinical Officers Council, and others.
Part IV – Registration, licensing and accreditation of health facilities – 48 (1)	Need for a unified license	Have a unified annual license to avoid multiple licensing by different authorities	A unified license would simplify compliance for healthcare providers and facilities. A unified system would help reduce financial strain
Part VII – General Provisions – 93(2) (h) & (l)	There's no clarity on the role on the pharmacies' standards, standards of alternative medicine and traditional medicine by the Board and PPB	Delete this section and maintain status quo in which the Pharmacy and Poisons Board, as currently authorized by CAP 244 continues to regulate these roles.	The Authority should allow the PPB with its established organization capacity and structures to regulate Pharmacy practice and minimize exposure

			of patients to harm that will happen should this role be stripped from PPB.
Page 47: Part VII – General Provisions – 94(2) (n)	Clarity on the role of PPB & the Board on this	We propose the deletion of this section, and for the functions to remain within PPB	The Authority should allow the PPB with its established organization capacity and structures to regulate Pharmacy practice and minimize exposure of patients to harm that will happen should this role be stripped from PPB.
Part VIII – Provisions on Delegated powers	Duplication of roles	To avoid duplication of roles and functions of existing health regulatory bodies – KMPDC, PPB, Nursing Council, e.t.c	Duplication of roles not only introduces ambiguity in enforcement of standards but also risks creating loopholes for non-compliance.
Part X – Transitional Provisions – Second Schedule (101)(1)(a)	Deleting of the definition of 'health care provider'	Replace the definition of 'health care provider' and replace with - **Heath care provider is a person duly qualified and licensed to provide health care services**	The revised definition ensures that only individuals who are **formally trained, certified, and licensed** by recognized regulatory bodies are considered healthcare providers.

Part X – Transitional Provisions – Second Schedule (101) (18)	No repeal of section 20 of CAP 244	Maintain status quo in the current CAP 244.	Repealing section 20 will interfere with the regulation of pharmacy practice in Kenya.
Part X – Transitional Provisions – Second Schedule (101) (21)	Delete Paragraph (m) in subsection 1. Retain Subsection 1, paragraph B, and any other paragraph.	While we agree with the deletion of paragraph (m) of Subsection 1, we recommend maintaining status quo for all the remaining paragraphs in Subsection 1.	Any other deletion in subsection 1 will affect the regulation of pharmacy practice and Health Products Technologies in Kenya. This will not only impact quality of the products and pharmacy care but also hinder PPB from achieving Maturity Level 3 and all the benefits this has for manufacturing ambitions for Kenya.
Part X – Transitional Provisions – 101- Second Schedule – Section 3B of CAP 244- Subsection 2 - deleting paragraph (i)	Deleting paragraph (i)	No deletion of paragraph (i) – maintain status quo of CAP 244	Deletion of this section will strip PPB powers in regulating manufacturing. Storage, distribution and even post marketing surveillance of pharmaceuticals in Kenya. This will not only impact quality of the products and pharmacy care but also hinder PPB from achieving

			Maturity Level 3 and all the benefits this has for manufacturing ambitions for Kenya.
Part X – Transitional Provisions – 101- Second Schedule - Section 3B of CAP 244- Subsection 2 - deleting paragraph (f)	Deleting paragraph (f);	No deletion of paragraph (f) – maintain status quo of CAP 244	Deleting of this section would mean that there's no longer an authorized register of medicines in Kenya. This will be detrimental to. Quality health, pharmaceutical care and will open up the market to unregulated products.
Part X – Transitional Provisions – 101- Section 3B of CAP 244- Subsection 2 - deleting paragraph (i)	Deleting paragraph (i);	No deletion of paragraph (i) – maintain status quo of CAP 244	This deletion takes away the authority of the PPB regulating the registration of health products and technologies and does not provide an alternative. This will not only impact patients access to quality, safe and effective health products and technologies but also hinder PPB from achieving Maturity Level 3

			and all the benefits this has for manufacturing ambitions for Kenya.
Part X – Transitional Provisions – 101- Section 3B of CAP 244- Subsection 2 - deleting paragraph (j)	Deleting paragraph (j);	No deletion of paragraph (j)	Deletion of this section will create a vacuum in regulation of pharmacy practice in Kenya. In the interim, there's going to be a vacuum which will introduce the market to uncertainties. This will also create a risk for patients, exposing them to harm. In addition, PPB already has the structures, institutional memory and capacity in this area. Therefore, stripping the Board of this power will lead to institutional capacity and memory loss.
Part X – Transitional Provisions – Second Schedule (101) (19)	Repeal of Section 23 of Cap 244	No repeal of Section 23 of Cap 244	Deletion of this section will take away the gains already made in combating illicit trade. It will create a vacuum that will

			open the market to unregistered and unregulated premises which will pose a risk to patients and result in the supply of illegitimate pharmaceutical products.
Part X – Transitional Provisions – Second Schedule (101) (20)	Repeal of Section 23A of Cap 244	No repeal of Section 23A of Cap 244	Repealing of this section would mean that any unlicensed or uncompliant premise will continue to operate because PPB will no longer have the power to close that premise.

We also propose the following:

- Maintaining the roles of other regulatory agencies in the health sector to avoid creating a vacuum and confusion in the industry that would expose patients to harm.
- We propose granting PPB more control as opposed to reducing its control, as this goes against the spirit of achieving WHO Maturity Level 3.
- Powers of the Board of the Authority and the Cabinet Secretary should be clearly defined to avoid overlapping of functions with the already established regulatory agencies, authorities, and boards.

Kind Regards,

Dr. James Mokoro.
KAPI Chairperson

National Gender and Equality Commission
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DDC & 3/9/25

NGEC/CS/LEGAL/VOL. II (19) **2nd September, 2025**

Mr. Arale
Please bring before DC Health
03/09/25

DIRECTORATE OF DEPARTMENTAL COMMITTEES
RECEIVED
03 SEP 2025

Mr. Samuel Njoroge, CBS
Clerk of the National Assembly
Clerk's Chambers
Parliament Building
P. O. Box 41842-00100
NAIROBI
cna@parliament.go.ke

Dear Mr. Njoroge

COMMENTS ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL N/A BILL NO 42 OF 2025

Reference is made to your call to submit memoranda on the Quality HealthCare and Patient Safety Bill 2025.

Section 8 (b) of the National Gender and Equality Commission Act, CAP7K mandates the Commission to, '*monitor, facilitate and advise on the integration of the principles of equality and freedom from discrimination in all national and county policies, laws, and administrative regulations in all public and private institutions*;

In line with its mandate, the Commission presents memoranda analyzing the proposed Bill and proposing amendments where necessary.

Yours

Purity Ngina, **PhD, MBS**
COMMISSION SECRETARY/ CEO

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NATIONAL GENDER AND EQUALITY COMMISSION

"Gender Equality and Non-Discrimination"

MEMORANDA: THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL NATIONAL ASSEMBLY BILL NO. 42 OF 2025

S/No	Clause	Proposed amendments	Justification
1.	**New proposed interpretations** Age appropriate	To interpret as follows-; **Age-appropriate"** means suitable for a particular age or age group	The term has been proposed in an amendment to clause 11(1)(b) below (serial No 7)
	Geriatrics	**Geriatrics"** means a specialized branch of medicine focused on the health care of older adults	Older persons face a lot of discrimination and negative bias in health facilities leading to poorer quality of care and reduced access to services. The Commission has applied the term through a proposed amendment to clause 15 on Right to Dignity and Equity (serial 7 below). Article 57(c)obligates the state to ensure older persons live in dignity and respect and be free of abuse

	non-informed consent	**"Non-Informed Consent"** occurs when an individual agrees to a medical procedure or study without being fully aware of the potential risks, benefits, and alternatives	The Commission has proposed sanctions in a new clause 10(4) under Clause 10-Right to informed consent. (serial No 6 below)
	Unauthorized medical procedures	"**Unauthorized medical procedure"** refers to a treatment or surgery on a patient without their explicit or informed consent and includes sterilizations, forced abortions, medical testing and procedures on intersex children and female genital mutilation.	Unauthorized medical procedures and non -informed consent constitute a large percentage of abuse and violation of the rights of special interest groups, including illiterate persons, persons with disabilities and intersex children.
	Reasonable Modification	**"Reasonable modification"** refers to physical changes to make it accessible for persons with special needs and includes ramps, grab bars, and wide doors.	The term has been applied in the proposed Bill in clause 8(2) (c) but not interpreted. To be interpreted for purposes of clarity
	Reasonable accommodation	**"Reasonable accommodation in healthcare"** refers to modifications or adjustments to policies, practices, or rules that enable individuals with special needs to have equal access to healthcare services and facilities, and includes accessible	To differentiate between modification and accommodation as applied in the Act The term has been proposed in clause 8 (2)(c)through an amendment (serial No 4 below)

		communication formats, appointments	The term has been applied in the proposed law in clause 8(2) (c) but has not been interpreted
	Special needs	**"Special needs"** include various forms of disability, advanced age, and intersex persons	"Special needs" has been applied in clause 8(c), but not interpreted
	Abuse and Violence	**Abuse and violence include the following** **Physical**, which includes hitting, kicking, pushing, or any physical assault that causes injury. **Verbal** involves shouting, name-calling, insults, threats, and other forms of abusive and derogatory language. **Psychological** includes intimidation, bullying, harassment, and humiliation. **Sexual abuse and violence** include unwanted sexual advances, harassment, sexual assault and rape.	The Commission deems it crucial to unpack the following terminologies " abuse and violence" The term has been applied in clause 8(d) The law needs to be clear on what abuse and violence entail and the sanctions thereto, as such cases have been on the rise against patients in many health facilities across the nation and need to be curbed

		Socio-economic factors involves actions that limit a patient's access to resources, care, or support, which impact their well-being	
2.	Clause 4 **Guiding principles** 4. The principles for implementation of this Act shall be — (a) equitable, quality, cost effective and accessible healthcare to all persons; (b) protection, promotion, improvement and maintenance of the health and well-being of every person; (c) patient-centered care; and (d) accountability	Amend by inserting an additional principle as follows-; (e) Promotion of a human rights-based approach to health care	The proposed Bill has not considered a rights-based approach to deal with patients To move away from charity and other models that put patients at the mercy of health workers. Rights-based means integrating human rights principles and standards in all aspects of health care Article 43(1)(a) of the Constitution provides the right that the proposed law seeks to implement. This principle is also very crucial in dealing with issues of persons with mental and psychosocial disabilities
3.	**Clause 5** **Role of the Cabinet Secretary** 5. The Cabinet Secretary shall—	Substitute the subtitle "Cabinet Secretary" with "National Government"	Obligations placement In line with the Functions of the National Government in the Fourth Schedule of the Constitution

	(a) develop and ensure implementation of policies, standards, guidelines and protocols that ensure the provision of quality healthcare services; (b) ensure continuous improvement in the quality of healthcare services provided to individuals for, or in connection with the prevention, (c).....		The proposal also aligns with Section 15 of the Health Act, which recognizes the functions as the National Government's functions
4.	**Clause 8** **Right to safe and accessible health facilities.** (2) Every health facility shall— (a) implement healthcare standards set out in this Act and other relevant laws; (b) ..... (c) provide reasonable modifications to enable accessibility by persons with special needs;	To amend 8(2) (c) by inserting after the phrase "modification" the following: "**and accommodation**	Reasonable accommodation has not been provided in the proposed law

			The Commission has proposed the interpretation of the two terms, i.e, accommodation and modification
	Proposed new sub-clause to clause 8	Insert a new clause 8(4) as follows-; (4) A health care worker who commits an offence under this section shall be liable, on conviction, to a fine not exceeding one hundred shillings or to imprisonment for a term not exceeding six months, or to both	The objectives of a law are to deter non-compliance and sanction the breach thereof There are no sanctions prescribed for abuse, violence, and or neglect
6.	**Clause 10** **Right to information and decision making** 10. (l) 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(l), every patient has the right to— (a) be provided with comprehensive details on diagnosis, treatment options and	Insert a new subclause 10(3) as follows-; 10 (3) A patient has the right not to be subjected to unauthorized and non-informed medical procedures	Cases of violation of the rights of patients has also been on the rise especially for women with various disabilities by health workers in collaboration with the family

	health products and technologies prescribed; (b) interpretation or alternative formats of information for accessibility; and (c) disclosure of risks and benefits of healthcare procedures.		
	Clause 10 **New proposed sub-clause on sanctions**	Amend by inserting another subclause (4) as follows-; (4)(a)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. (b) The health worker will face sanctions from their respectful professional bodies (c) The patient can institute civil proceeding to recover damages	
7.	**Clause 11** **Right to timely and effective care**	Propose to amend clause 11 1(b) by inserting the phrase " and age" after the phrase "needs"	The intersectionality of the age of patients is very crucial in matters of health care, including in reproductive health care, early childhood development, nutrition, healthy lifestyle, chronic sicknesses, etc.

	11. (l) Every person has the right to access quality safe and healthcare services that are— (a) safe and dignified; (b) appropriate to their clinical needs; and (c) compliant with quality of healthcare standards prescribed under this Act	Amend by inserting a new subclause (2) as follows-; (2) A person shall not be denied emergency treatment Any medical institution that fails to provide emergency medical treatment while having ability to do so commits an offence and is liable upon conviction to a fine not exceeding three million shillings.	Article 43(3) of the Constitution
New proposed provisions on the rights of patients			
8.	Proposed new clause on the Rights of persons under incarceration	**To insert as follows-;** All correctional facilities shall ensure that all persons under incarceration have access to timely and quality healthcare Clause 94 on Regulations to be amended to mandate the Cabinet Secretary to make regulations on access to health care by persons in incarceration	The Right in Article 43 needs to protect the rights of all persons, including those who are in prison and correctional facilities. The Nelson Mandela Rules are internationally recognized guidelines that promote the health Rights of Prisoners
9.	New provision on the **right of discharge from health Facilities**	**Amend by inserting a new clause as follows-;**	To ensure that once a patient is due for discharge, the same should be expedited and any other pending

		a. Every patient has the right to be discharged from a health facility once they are medically fit for discharge b. Health facilities shall take all reasonable steps to prevent unnecessary delays that may prolong a patient's stay beyond their medical needs c. Under no circumstances shall a facility detain or deny discharge to a patient on account of failure to pay hospital fees	matters to be attended to while out of hospital. Some health facilities detain patients who are unable to settle the fees and ironically continue charging them inflating the amount even further
10	**Clause 15** **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,	Amend clause 15(2)(a) by inserting after the phrase "including" the following-; "geriatric care," Amend clause 15(2) (c) by inserting after the phrase "disabilities" the following:" older members of society and Intersex persons" Amend by deleting the phrase "minority groups" without replacement	Older members of society and intersex persons are not included Health care needs to specifically focus on older members of society because of the increased health complications and intersex persons who are very vulnerable and susceptible to multiple discrimination

	ethnicity, health status or socioeconomic status; and (c) tailored services marginalized for vulnerable or groups, including women, youth, persons with disabilities and minority groups.		The Constitution of Kenya, in Article 260, by way of deduction, defines marginalized groups to include minority groups. It does not provide for an express interpretation of "Minority groups,"
11	**Clause 24** **Professional indemnity** 25. (1) Every health facility shall maintain a valid professional indemnity cover to protect the health facility against claims arising from acts or omissions committed in the course of providing healthcare services.	The applicability of professional indemnity	Substantiate whether professional indemnity is applicable to both public and private health facilities and consider making an exception to government health facilities but providing a mechanism by an easy to access, procedurally simplified and expeditious process for aggrieved patients to follow. The process under the Kenya Medical Practitioners and Dentist Council faces severe challenges including: **1. Accessibility and Awareness:** • The process is not well-publicized, and many stakeholders including patients and healthcare workers who are unaware of how to lodge complaints or follow up on them. 2. **Undefined Timelines**:

			• Although the Council states that it aims to resolve matters "at the shortest time possible," there are no **statutory timelines** for each stage of the complaint process. 3. **Overly Technical Procedures**: • The disciplinary rules (e.g., Legal Notice No. 171 of 2022) involve formal inquiries, notices, and hearings that resemble court proceedings. 4. **Lack of Transparency**: • There is minimal public reporting on the outcomes of disciplinary cases. It's unclear how many complaints are received, investigated, or result in sanctions.
12	**Clause 29** **Board of Directors of the Authority** 29. (l) The management of the Authority shall vest in a Board of Directors consisting of—	Amend clause 29(1)(h) by substituting the proposed appointee with "One person representing persons with disability nominated by the umbrella organization of persons with disabilities	The proposed person is ambiguous and does not provide a criteria for the nomination. The proposal by the Commission aligns with the principle of inclusion of persons with disabilities and also provides a criterion for nomination.

	(a) a chairperson appointed by the President; (b) The Principal Secretary in the Ministry for the time being, responsible for matters relating to quality of healthcare standards or a representative designated in writing; (c) the Principal Secretary for the National Treasury or a representative designated in writing; (d) the 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; (g) one person appointed by the Cabinet Secretary, not being a	**Amend clause 29 further by providing for-** a. gender balance and representation of persons with disabilities b. appointment of directors in a staggered manner to ensure Board business does not stagnate at any given time	Non-compliance with Mwongozo code for governance and the Constitution on inclusion and equality Principle of gender balance and representation of Disability

	public officer, to represent healthcare providers; (h) one person appointed by the Cabinet Secretary to represent the public; and (i) the Chief Executive Officer, who shall be an ex officio member of the Board. (2) The appointment of the chairperson and members under subsection (l)(e), (f) and (g) shall be by notice in the Gazette.		
13.	Clause 31- Term of office 31. (1) The chairperson and the members appointed Term of office. under section 29 (1) (D, (g) and (h) 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	Amend by providing grounds of vacation of office as follows-: (a) Resignation (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	The provision has not been provided in the Bill

		(f) violation of the Constitution or any other written law; or	
14.	**Clause 36** **Removal from office of the Chief Executive Officer.** 36. (1) The Chief Executive Officer may be removed from office by the Board in accordance with the terms and condition of service, for-- (a) inability to perform the functions of the office arising out of physical or mental infirmity; **(f).** Being declared as being of sound mind	Amend by deleting the provision in 36 (a) and (f) that refer to mental infirmity and unsound mind	Vacation of office by the Board members and the Chief Executive Officer on the grounds of mental infirmity or unsound mind is prejudicial to persons. The bill is, on one hand, proposing the rights of all patients, including persons with mental disabilities, while on the other, it is discriminating against them by referring to them in derogatory terms like "unsound mind." The Ministry of Health has rolled out the WHO Quality Rights Initiative, which seeks to improve the quality of mental health and protect the rights of persons with mental health conditions. The Convention on the Rights of Persons with Disabilities also provides for reasonable accommodation, and if it is no longer viable, then the due process of separation takes its course.

			This ground does not need to be legislated in all frameworks because it is discriminatory and prejudicial against persons with various forms of disabilities
16.	**Clause 94** **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 from the date 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.	Amend clause 94(2) by substituting "60 days" with "30 days"	The period of 60 days in 94(2) is too long and unjustifiable, depending on the subject of the review
17.	**Clause 98** **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	Amend Clause 98 by substituting "ten Million" with "one hundred thousand" and "ten years" with "six months"	The general penalty for unidentified offences is ambiguous and excessive in the circumstances. We note that the penalties for identified offences in Clauses 78,82, and 97 are way below the proposed penalty in this provision

DDC
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27/08/25

MEMORANDUM ON THE QUALITY HEALTHCARE AND PATIENT SAFETY BILL, 2025

Hassan Arale
Pls bring to the attention of Committee
29/08/25

Submitted to:
The Clerk of the National Assembly
P.O. Box 41842-00100
NAIROBI, Kenya

Adan Gindicha Approved for forwarding
for deal
28/8/25

From:
George Otieno Agal
P.o.Box 3817-40100
Kisumu

GEORGE OTIENO AGAL
P.O. Box 3817-40100
Kisumu, Kenya
Email: agalbilly
Date: 25/08/25 Sign:

25th August,2025

1. Introduction

I, **George Otieno Agal**, a citizen of Kenya, make this submission in exercise of my constitutional right to participate in law-making under Article 118(1)(b) of the Constitution. I welcome the introduction of the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025) as it seeks to give effect to Article 43(1)(a) of the Constitution, which guarantees the right to the highest attainable standard of health.

2. General Support

I strongly support the Bill because it:

- Establishes a framework for ensuring safe, high-quality healthcare services for all Kenyans.
- Provides for the creation of a Quality Healthcare and Patient Safety Authority to oversee standards.
- Ensures that health facilities are licensed, accredited, and regularly monitored.
- Places responsibility on both the national and county governments to guarantee quality healthcare.

3. Key observations and recommendations

a) On Patient rights

- The Bill rightly emphasizes the rights of patients to dignity, safety, and information.
- I recommend that the Authority develop a Patient Rights Charter to be displayed in all health facilities for public awareness.

b) On Accountability of health workers

- The Bill requires healthcare providers to follow ethical and professional standards.
- I recommend clear penalties for negligence or malpractice, alongside mechanisms to protect whistleblowers who report unsafe practices.

c) On Licensing and accreditation of facilities

- Regular inspection is vital to ensure compliance.

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P O Box 41842, NAIROBI

DIRECTORATE OF DEPARTMENTAL COMMITTEES
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- I propose mandatory public reporting of inspection results, so citizens can make informed choices on where to seek care.

d) On complaints and redress mechanisms

- The Bill provides for complaints handling.
- I recommend a toll-free hotline and digital reporting system to make it easy for citizens to raise concerns.

e) On Patient safety systems

- Reporting and learning from medical errors is a progressive step.
- I propose that anonymized data on patient safety incidents be published annually to encourage system-wide learning and accountability.

f) On resourcing the authority

- For the Authority to be effective, it must be adequately funded and staffed.
- I recommend that Parliament ensures budgetary allocation is ring-fenced for patient safety and quality improvement.

4. Conclusion

The Quality Healthcare and Patient Safety Bill, 2025 is a timely and necessary piece of legislation that will significantly improve health outcomes in Kenya. By embedding patient safety and quality as legal requirements, it ensures that Kenyans will be protected from preventable harm and can access healthcare that is safe, dignified, and of high standard.

I urge the National Assembly to consider the recommendations highlighted above to strengthen the Bill further.

Respectfully submitted,

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