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Rt. Hon. Speaker
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Clerk of the Senate/Secretary, PSC
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THE SENATE

STANDING COMMITTEE ON HEALTH

REPORT OF THE STANDING COMMITTEE ON HEALTH ON
CONSIDERATION OF THE QUALITY HEALTHCARE AND PATIENT
SAFETY BILL, 2025 (NATIONAL ASSEMBLY BILLS NO. 41 OF 2025)

Clerks Chambers,
Parliament Buildings,
NAIROBI.

17/09/26
APPROVED
RT. HON. SEN
AMASON J. KINGI

September, 2026

PAPERS LAID	
DATE	22/9/2026
TABLED BY	Vive chair.
COMMITTEE	Health
CLERK AT THE TABLE	Cherop

Mr. Hon. Speaker
You may wish to know
that the committee has
just received a letter
from the President
of the United States
dated January 1, 1950
in which he has
expressed his
confidence in the
committee's work.

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JAN 1 1950
U.S. HOUSE OF REPRESENTATIVES

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LIST OF ABBREVIATIONS

BGMA	Bachelor of Clinical Medicine Graduates Association
BCMGA	Bachelor of Clinical Medicine Graduates Association
COFPAK	Confraternity of Patients Kenya
CoG	Council of Governors
KCOA	Kenya Clinical Officers Association
KEHPHPU	Kenya Environmental Health and Public Health Practitioners Union
KELIN	Kenya Legal and Ethical Issues Network on HIV and AIDS
KMA	Kenya Medical Association
KMPDU	Kenya Medical Practitioners, Pharmacists and Dentists Union
KNUMLO	Kenya National Union of Medical Laboratory Officers
KNUPT	Kenya National Union of Pharmaceutical Technologists
KUCO	Kenya Union of Clinical Officers
KUNAD	Kenya Union of Nutritionists and Dieticians
LMSK	Lab Medicine Society of Kenya
PSK	Pharmaceutical Society of Kenya
RAPSK	Regulatory Affairs Professionals Society of Kenya
RUPHA	Rural and Urban Private Hospitals Association of Kenya
TPAK	The Paramedic Association of Kenya

PRELIMINARIES

Establishment and Mandate of the Committee

The Standing Committee on Health is established pursuant to standing order 228 (3) and the Fourth Schedule of the Senate Standing Orders and is mandated to *consider all matters relating to medical services, public health and sanitation.*

Pursuant to Standing Order 228(4), the Committee is specifically mandated to-

- 1) *investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration and operations of the Ministry of Health and its departments;*
- 2) *study the programme and policy objectives of the Ministry of Health and its departments, and the effectiveness of the implementation thereof;*
- 3) *study and review all legislation referred to it;*
- 4) *study, assess and analyze the success of the Ministry of Health and departments assigned to it as measured by the results obtained as compared with their stated objectives;*
- 5) *consider the Budget Policy Statement in line with the Committee's mandate;*
- 6) *report on all appointments where the Constitution or any law requires the Senate to approve;*
- 7) *make reports and recommendations to the Senate as often as possible, including recommendations for proposed legislation;*
- 8) *consider reports of Commissions and Independent Offices submitted to the Senate pursuant to the provisions of Article 254 of the Constitution;*
- 9) *examine any statements raised by Senators on a matter within its mandate; and*
- 10) *follow up and report on the status of implementation of resolution within its mandate; and*
- 11) *follow up and report on the status of commitments made by the Cabinet Secretaries in their response to questions under Standing Order 51C*

Committee Membership

The Committee is comprised of the following members-

- | | | |
|---|---|-------------------------|
| 1. Sen. Jackson K. Arap Mandago, EGH, MP | - | Chairperson |
| 2. Sen. Mariam Sheikh Omar, MP | - | Vice-Chairperson |
| 3. Sen. Justice (Rtd.) Stewart Madzayo, EGH, MP | - | Member |
| 4. Sen. Ledama Olekina, CBS, MP | - | Member |
| 5. Sen. Richard Onyonka, MP | - | Member |
| 6. Sen. Tabitha Mutinda, CBS, MP | - | Member |
| 7. Sen. Hamida Kibwana, MP | - | Member |
| 8. Sen. Abdalla Shakila Mohamed | - | Member |
| 9. Sen. Vincent Kiprono Cheburet Chemitei, MP | - | Member |

CHAIRPERSON'S FOREWORD

The Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bills No. 41 of 2025) was passed by the National Assembly, with amendments, on Tuesday, 2nd June, 2026 and referred to the Senate for consideration. Consequently, the Bill was introduced in the Senate by way of First Reading on 15th July, 2026 and thereafter stood committed to the Standing Committee on Health for consideration.

The Bill seeks to give effect to Article 43 (1) (a) of the Constitution by establishing the Quality Healthcare and Patient Safety Authority, providing for the registration, licensing, accreditation and inspection of health facilities, setting standards for quality healthcare, guaranteeing patient rights and patient safety and establish a Health Care Tribunal.

The Bill seeks to separate the regulation of healthcare facilities from the regulation of healthcare professionals and sets standards for quality healthcare, guarantees patient rights and safety, establishes the Quality Healthcare and Patient Safety Authority to be in charge of health facilities registration, licensing and accreditation and establishes a Healthcare Tribunal responsible for adjudicating disputes arising from the implementation of the Act. Together, these provisions build a comprehensive legal and institutional framework for the promotion and continuous improvement of healthcare quality in Kenya.

Pursuant to Article 118 of the Constitution and standing order 145 (5) of the Senate Standing Orders, the Committee invited interested members of the public to submit any representations that they may have on the Bill by way of written memoranda through public advertisements that appeared on *the Daily Nation and the Standard Newspapers* on Tuesday, 21st July, 2026. At the close of the public participation period, the Committee prepared a comprehensive matrix of all submissions, views and proposed amendments for its consideration.

During the consideration of the Bill, the Committee observed that Kenya's health sector has long grappled with heightened cases of medical negligence, inconsistent standards of care, fragmented regulation of healthcare professionals and health facilities, and a growing number of unlicensed facilities operating with limited oversight. This is largely attributable to the absence of a single statute consolidating standard-setting, licensing, accreditation, inspection and enforcement of healthcare quality and safety.

The Committee further observed that healthcare facilities are presently licensed under various professional regulation statutes such as the Medical Practitioners and Dentists Act, the Clinical Officers Act and the Nurses and Midwives Act with each Council regulating premises incidental to its own profession. Further, no statute provides measurable quality healthcare standards, provides for accreditation of health facilities, requires adverse event reporting or gives enforceable set of patient rights against a healthcare facility.

The Bill therefore seeks to cure this legislative gap, giving effect to Article 43(1)(a) of the Constitution and ensuring that quality healthcare and patient safety is realized as part of the attainment of Universal Health Coverage. The Bill also draws a clear line between health facilities regulation and health professionals' regulation.

The Quality Healthcare and Patient Safety Authority will be responsible for the regulation of health facilities while the Kenya Health Professions Oversight Authority established under the Health Act, and the respective health professionals' regulatory bodies such as the Kenya Medical Practitioners and Dentists Council and the Clinical Officers Council retaining the powers to regulate healthcare professionals.

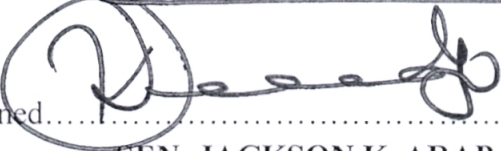
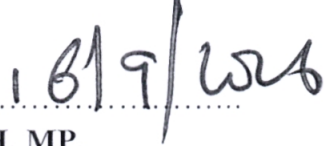
The Bill further empowers the Quality Healthcare and Patient Safety Authority to conduct both announced and unannounced health facility visits to ensure that quality of care and patient safety standards are adhered to by all healthcare facilities in the country.

The Bill therefore mandates the Authority to appoint inspectors responsible for conducting hospital visits. Where any health facility is found noncompliant with the standards established under this law, the Authority is empowered to close the facility.

With the foregoing, the Committee therefore recommends that the Senate passes the Bill with the proposed amendments.

As I conclude, I wish to sincerely thank the Office of the Speaker and the Office of the Clerk of the Senate for the support extended to the Committee in execution of its mandate. I also wish to extend my gratitude to the Committee members for their diligence, commitment and insightful contributions throughout consideration of this Bill.

It is now my pleasant duty, pursuant to standing Order 148 (I) Of the Senate Standing Orders, to present the Report of the Standing Committee on Health on its consideration of the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bills No. 41 of 2025).

Signed.......... Date..........
SEN. JACKSON K. ARAP MANDAGO, EGH, MP,
CHAIRPERSON, STANDING COMMITTEE ON HEALTH.

CHAPTER ONE

1.0 INTRODUCTION

1. The Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bills No. 41 of 2025) was passed by the National Assembly, with amendments, on Tuesday, 2nd June, 2026. The Bill was introduced in the Senate by way of First Reading on Wednesday, 15th July, 2026 and thereafter stood committed to the Standing Committee on Health for consideration. A copy of the Bill as published and introduced to the Senate has been annexed to this report as *Annex 2*.
2. Pursuant to standing order 145 of the Senate Standing Orders, the Committee is required to facilitate public participation and to consider the views and recommendations of the public when it submits its report to the Senate.
3. The principal object of the Bill is to give effect to Article 43(1)(a) of the Constitution by establishing a comprehensive legal and institutional framework for the promotion, regulation and continuous improvement of the quality of healthcare in Kenya.
4. The Bill sets out patient rights and corresponding facility obligations, establishes the Quality Healthcare and Patient Safety Authority to register, license, accredit and inspect health facilities, creates a specialized Health Care Tribunal to resolve health-sector disputes and prescribes offences and penalties for non-compliance with the provisions of the Act.
5. In accordance with the provisions of Article 118 of the Constitution and Standing Order 145 (5) of the Senate Standing Orders, the Committee invited interested members of the public to submit any representations that they may have on the Bill by way of written memoranda through public advertisements that appeared on the *Daily Nation* and the *Standard Newspapers* on Tuesday, 21st July, 2025. Copies of the advertisements as published have been attached to this report as *Annex 3*. The memoranda were to be received by the Senate on or before Monday, 3rd August, 2026 at 5:00 p.m.

1.1. Background

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

7. This is largely attributed to the lack of a single statute consolidating standard-setting, licensing, accreditation, inspection and enforcement in relation to healthcare quality and safety, nor a dedicated framework guaranteeing patients enforceable rights and a clear avenue for redress. This has left patients vulnerable to substandard care and undermined public trust in both public and private health facilities.
8. The right to the highest attainable standard of health, including reproductive health care, is guaranteed under Article 43(1)(a) of the Constitution of Kenya, 2010. At the statutory level, aspects of healthcare regulation are currently addressed in a fragmented manner across the Health Act (Cap. 241), the Public Health Act (Cap. 242), and a range of professional-regulation statutes, including the Medical Practitioners and Dentists Act (Cap. 253), the Nurses and Midwives Act (Cap. 257), the Pharmacy and Poisons Act (Cap. 244), and the Clinical Officers (Training, Registration and Licensing) Act (Cap. 260), each of which regulates a specific cadre of health professionals or facility type.
9. There is no harmony in the quality and patient-safety framework, and complaints-handling, standard-setting and facility-level enforcement are similarly spread among various regulatory bodies, resulting in overlapping mandates and regulatory gaps.
10. The Bill is anchored on Article 43(1)(a) of the Constitution and seeks to consolidate the currently fragmented regulatory landscape into a single, coherent framework anchored on patient rights, evidence-based standards, and predictable enforcement, while also aligning Kenya's health quality assurance systems with international best practice and complementing the Social Health Insurance Act, 2023 and the Digital Health Act, 2023.

1.2. Objectives of the Bill

11. The principal object of the Bill is to give effect to Article 43(1)(a) of the Constitution by providing for the responsibility of the national and county governments in the realization of quality healthcare for patients; the establishment, powers and functions of the Quality Healthcare and Patient Safety Authority; the registration, licensing and accreditation of health facilities; the setting of standards for quality healthcare; creates a specialized Health Care Tribunal to resolve health-sector disputes, and prescribes offences and penalties for non-compliance with the provisions of the Act.

1.3. Overview of the Bill

12. The Quality Healthcare and Patient Safety Bill, 2025 is organized into ten (10) Parts and the First and Second Schedules.
13. **Part I** of the Quality Healthcare and Patient Safety Bill, 2025 provides for the preliminary matters including the short title, definitions, objects of the Bill, the guiding principles and the roles of the Cabinet Secretary for Health and County Governments. It lays the foundation for the entire legislation by defining its scope, intent, and guiding principles. It establishes a coherent governance and coordination framework between the national and county levels, ensuring clarity in roles, responsibilities, and accountability in the delivery of quality healthcare services.
14. Clause 1 provides for the short title of the Bill, citing it as the Quality Healthcare and Patient Safety Act, 2025. Clause 2 provides for the definitions of specialized terms used within the text of the Bill to facilitate a comprehensive understanding of its provisions. Clause 3 provides for the objects of the Bill, which include protecting patient rights and safety, setting and monitoring healthcare standards, improving the quality and outcomes of healthcare, and ensuring the delivery of safe, effective, and efficient care.
15. Clause 4 of the Bill sets out the guiding principles for the implementation of the Bill, emphasizing equitable, quality, cost-effective, and accessible healthcare; the promotion of individual health and well-being; patient-centered care; and accountability in healthcare delivery. Clause 5 of the Bill provides for the roles of the Cabinet Secretary for Health in the delivery of quality healthcare services, including the development of policies, standards, guidelines, and protocols to ensure the provision of quality healthcare services.
16. Clause 6 provides for the roles of County Governments, which include implementing the national government policies, guidelines, protocols, and standards.
17. **Part II** of the Bill establishes the rights and safety guarantees for patients. It affirms patients' rights to safe, quality, timely, and equitable healthcare services; access to information; dignity; and participation in decision-making. It obligates health facilities and professionals to uphold patient safety standards, ensure competent service delivery, and maintain safe processes and practices.

18. It further provides for a Patient Rights Charter, safety and quality assurance measures, risk management, professional indemnity, and continuous quality improvement. Patients are also assigned duties, including cooperation with health providers and adherence to facility rules.
19. Clause 7 requires national and county governments to progressively realize the patient rights in the legislation and empowers the Cabinet Secretary to make supporting policies and regulations. Clause 8 guarantees patients the right to safe, accessible health facilities and obliges facilities to meet high environmental, sanitation and accessibility standards. Clause 9 confirms the right to care by qualified, licensed health professionals with verified credentials. Clause 10 secures the patient's right to clear, comprehensive and accessible information to enable informed decision-making. Clause 11 affirms the right to safe, appropriate and standards-compliant quality care and provides for redress where rights are violated.
20. Clause 12 ensures the right to timely and effective care, including prompt access, coordinated continuity and timely referrals. Clause 13 guarantees safe clinical processes and standardized patient-identification and documentation protocols. Clause 14 protects the right to safe and quality health products and technologies and requires providers to follow regulatory laws and report adverse reactions. Clause 15 safeguards the right to dignity and equitable, non-discriminatory care, including tailored services for vulnerable groups and clause 16 establishes the right to be heard, to report concerns, receive explanations, redress and protection from retaliation; and requires health facilities to provide internal complaints mechanisms.
21. Clause 17 requires health facilities to develop and display a Patient Rights Charter using an Authority-issued template. Clause 18 mandates patient safety and quality assurance measures at facility level and sets penalties for non-compliance i.e., a fine not exceeding ten million shillings. Clause 19 imposes a duty on facilities to uphold prescribed quality-of-care standards, with enforcement by the Authority. Clause 20 requires adherence to evidence-based clinical guidelines, to be developed and published by the Director-General for Health.
22. Clause 21 obligates health facilities to implement infection prevention, safe product/technology systems and to report adverse events through the Comprehensive Integrated Health Information System established under the Digital Health Act.

23. Clause 22 requires the Cabinet Secretary for Health to issue a national quality improvement framework and obliges facilities to implement quality programs and report progress. Clause 23 requires County Governments and health facilities to verify staff qualifications and provide periodic training on safety and quality.
24. Clause 24 mandates professional indemnity cover for health facilities and verification that staff are insured and clause 25 lists duties of patients including following health facility rules, giving accurate information, treating staff respectfully and signing discharge/release when refusing recommended care.
25. Part II therefore seeks to place patients at the centre of the healthcare system by safeguarding their rights, dignity, and safety. It promotes a culture of accountability, continuous quality improvement, and patient engagement, thereby strengthening trust between healthcare providers and the public.
26. **Part III** on the other hand, establishes the Quality Healthcare and Patient Safety Authority as a corporate body responsible for regulating the delivery of quality of healthcare. It outlines the Authority's functions, including registration, licensing, accreditation, inspections, and enforcement of quality standards. It also defines the composition, powers, and duties of the Authority's Board of Directors, qualifications and tenure of members, establishment of committees, delegation of powers, and appointment of the Chief Executive Officer, Corporation Secretary, and other staff. It also covers remuneration, protection from personal liability, and use of the common seal.
27. Clause 26 establishes the Quality Healthcare and Patient Safety Authority as a corporate body. Clause 27 enumerates the Authority's functions including regulation, registration, licensing, accreditation and inspection of health facilities, monitoring, public awareness and capacity building. Clause 28 grants the Board all powers necessary to perform its functions, including financial and partnership powers. Clause 29 constitutes the Board of Directors including appointed and ex-officio members. Clause 30 sets minimum qualifications for appointment as Chairperson or appointed Board member and clause 31 specifies terms of office (three years) and reappointment rules for Board members.
28. Clause 32 permits the Board to establish committees and co-opt expertise for committee work. Clause 33 provides for the Board's conduct of business and procedures in accordance with the First Schedule. Clause 34 enables the Board to delegate powers by resolution to committees or members.

29. Clause 35 requires the Board to appoint a Chief Executive Officer (CEO) through an open, competitive process and lists CEO qualifications and responsibilities. Clause 36 provides grounds and fair-process requirements for removing the CEO. Clause 37 provides for appointment, qualifications and roles of the Corporation Secretary. Clause 38 empowers the Board to employ staff through transparent recruitment and set terms of service and clause 39 prescribes remuneration arrangements for the Board and staff, subject to the advice of the Salaries and Remuneration Commission (SRC).
30. Clause 40 protects Board members and staff from personal liability for good-faith acts, while preserving liability for unlawful acts and clause 41 provides for the Authority's common seal and its authentication.
31. The aforementioned part provides the institutional framework for managing healthcare quality through the establishment of the Quality Healthcare and Patient Safety Authority. It ensures that regulation, oversight, and enforcement of quality standards are carried out in a structured, transparent, and coordinated manner across the country.
32. **Part IV** provides the regulatory framework for the approval, registration, licensing, and accreditation of health facilities. It prescribes requirements for establishing, operating, or decommissioning facilities and sets procedures for obtaining approvals, registration certificates, and licences. It details standards for categorization of facilities, accreditation processes, quality scoring, and rating. The Part empowers the Authority to monitor compliance, suspend or revoke licences or accreditations, and maintain a national register of health facilities.
33. This part operationalizes quality assurance by providing a structured system for the registration, licensing, and accreditation of health facilities. It ensures that all health facilities meet defined standards before offering services and remain accountable for maintaining high-quality care throughout their operations.
34. Clause 42 requires prior Authority approval to construct, operate or decommission health facilities and empowers the Cabinet Secretary to set requirements for health facilities, ambulances and medical camps. Clause 43 requires registration of any health facility that intends to operate, following the Authority's approval. Clause 44 prescribes required documentation including contact details of the health facility's owner and inspection prior to issuing registration certificates and clause 45 provides for issuance of certificates of registration, payment of fees, and written notice of refusal with reasons.

35. Clause 46 sets grounds and procedures for suspension of a registration certificate and provides appeal rights. Clause 47 sets grounds and procedures for revocation of registration and requires Gazette publication of revocations. Clause 48 requires registered facilities to apply for annual licences and makes operation without a licence an offence with penalties. Clause 49 lists documents and information required when applying for a licence including a copy of the certificate of registration issued to the health facility. Clause 50 specifies criteria for grant of a licence (premises, staff licensure, qualifications and compliance with quality standards).
36. Clause 51 provides for licence validity (until 31st December of each year) and renewal procedure. Clause 52 categorizes health facilities as per the First Schedule to the Health Act and classifies ambulances by their respective capacities. Clause 53 requires licences to specify permissible services, while allowing emergency care in accordance with Regulations prescribed by the Cabinet Secretary for Health. Clause 54 sets out suspension procedures for licences, notice and appeal rights and clause 55 sets out revocation procedures for licences, notice, opportunity to respond and penalties for operating after revocation.
37. Clause 56 provides for accreditation of registered, licensed facilities for quality of healthcare. Clause 57 defines the Authority's role in accreditation, appointing quality assessors to conduct the accreditation, publicizing standards and collaborating for assessments. Clause 58 prescribes application procedures for accreditation, including required self-assessment and supporting documents such as a description of the type and level of health facility. Clause 59 lists accreditation criteria including standards compliance, infrastructure, Human Resource (HR), clinical guidelines, products/technology, patient outcomes and satisfaction monitoring and clause 60 provides for issuance of a certificate of accreditation when requirements are met.
38. Clause 61 sets validity of the accreditation certificate (two years). Clause 62 requires that an application for the renewal of accreditation be submitted ninety (90) days before the expiry of the existing accreditation. Clause 63 allows the Authority to suspend accreditation for non-conformity, non-rectification or legal non-compliance and provides notice and appeal procedures. Clause 64 allows revocation of accreditation for fraud, non-rectification or concealment, with Gazette publication and appeal rights.

39. Clause 65 requires facilities to keep records of quality improvement activities, set improvement programs and conduct self-assessments and clause 66 directs the Authority to establish a quality scoring and rating framework and to publish assessment results.
40. Clause 67 provides for awarding performance ratings and recognition certificates tied to assessment results and incentives. Clause 68 lists actions for non-compliance (warnings, corrective programs, fines, suspension/revocation of accreditation, and closure where immediate risk exists). Clause 69 requires the Authority to monitor compliance with accreditation requirements. Clause 70 requires the Authority's CEO to maintain a register of registered, licensed and accredited facilities with specified details including the type and nature of healthcare services provided by the facilities and clause 71 allows removal from the register for fraud, Board direction, or failure to meet accreditation requirements, and provides for correction of errors.
41. On its portion, **Part V**, mandates the appointment of inspectors and outlines their qualifications, powers, and code of conduct. It provides for inspection objectives and programmes both routine and unannounced to ensure compliance with the legislation. It further prescribes enforcement measures, penalties for obstruction, temporary closures, and oversight responsibilities of the Authority in addressing violations. It strengthens regulatory compliance by empowering the Authority to conduct inspections, investigate complaints, and enforce corrective actions. It provides an effective mechanism for identifying and addressing risks, thus safeguarding patient safety and promoting continuous improvement in healthcare delivery. Part V also emphasizes accountability, transparency, and fair administrative action in enforcement proceedings.
42. Clause 72 authorizes Gazette-appointment of facility inspectors and sets their basic inspection duties. Clause 73 requires the Authority to establish planned routine and reactive inspection programmes that are announced and unannounced. Clause 74 grants inspectors' powers of entry, search, sampling, and interview in performance of their duties. Clause 75 prescribes appointment of qualified inspectors by Gazette Notice. Clause 76 details conduct of inspections, reporting, and use of inspection reports for suspension of registration or licensing, or closure recommendations. Clause 77 requires the Authority to prescribe a code of conduct for inspectors and Clause 78 creates offences and penalties including for obstructing inspectors or impersonating the Authority or an inspector.

43. Clause 79 enables inspectors to order immediate temporary suspension of services/facilities posing immediate risk and to take other prescribed enforcement actions. Clause 80 sets the Authority's oversight role on inspection reports, objection review, remedial orders, temporary closures and penalties, with requirements for remedy and prevention of recurrence for the persons subject to enforcement action.
44. Clause 81 requires facilities to keep records of services, inspection recommendations and mitigation measures and clause 82 allows the Authority to specify records to be kept and to require their production; with refusal to comply attracting penalties.
45. **Part VI** establishes the Health Care Tribunal, defines its jurisdiction, and provides for dispute resolution mechanisms arising from implementation of the legislation. It outlines procedures for filing appeals and managing vacancies within the Tribunal, ensuring access to administrative justice for aggrieved parties. It ensures access to justice and fairness within the health sector by establishing an independent Tribunal to resolve disputes and hear appeals arising from the implementation of the legislation. It enhances accountability and reinforces confidence in regulatory decisions and healthcare governance.
46. Clause 83 establishes the Health Care Tribunal and prescribes its composition, appointment, term and quorum. Clause 84 provides for the Tribunal's jurisdiction (original and appellate) over health-sector disputes under this and other Acts, excluding criminal trials, and recognizes its power to grant equitable remedies.
47. Clause 85 provides for appeals to the Tribunal against decisions or actions under the legislation within 21 days and allows the Tribunal to uphold, vary or reverse decisions. Clause 86 provides for vacancies in the Tribunal and sets out the grounds upon which the office of a member becomes vacant, including instances where a member dies or resigns.
48. **Part VII** sets out the financial management framework of the Authority. It provides for funding sources, investment of funds, preparation of annual estimates, accounts, audits, and submission of annual reports. It ensures financial integrity, transparency, and sustainability of the Authority's operations. By setting out clear mechanisms for funding, budgeting, and auditing, it promotes efficient use of resources to support the regulation and improvement of quality of healthcare nationwide.

49. Clause 87 specifies the Authority's funds and sources including monies appropriated by the National Assembly, fees, grants and other monies. Clause 88 permits investment of surplus funds. Clause 89 provides for the Authority's financial year. Clause 90 requires preparation and approval of annual estimates and budgeting processes and clause 91 requires proper accounts and audit of the Authority's finances and compliance with audit requirements of the Authority.
50. Clause 92 requires the Authority to prepare and submit to the Cabinet Secretary for Health an annual report on the operations of the Authority for the immediately preceding year.
51. **Part VIII** provides for the Cabinet Secretary's power to make Regulations for the effective implementation of the legislation. It therefore establishes the delegated legislative framework necessary to operationalize the legislation by enabling the development of detailed procedures, standards, and administrative requirements that facilitate its effective implementation and enforcement.
52. **Part IX** sets out the general provisions necessary for the effective operation of the Act. It provides for review and appeal mechanisms, imposes confidentiality obligations, and prescribes offences and penalties for non-compliance. It provides the operational and enforcement backbone for the legislative framework. By establishing review mechanisms, confidentiality safeguards, and penalties, it ensures that the Act is fairly administered and adequately enforced. It strengthens compliance, promotes transparency, and upholds the integrity of healthcare governance and patient safety standards.
53. **Part X** provides for transitional arrangements and consequential amendments necessary for the seamless implementation of the Act. It guarantees a smooth and orderly transition from the existing legal and institutional frameworks to the proposed framework under the Quality Healthcare and Patient Safety Bill, 2025. It safeguards continuity of operations, prevents duplication of regulatory processes, and ensures harmony across the broader health-sector legislative environment.
54. The **First Schedule** of the Bill provides detailed rules for the conduct of business and affairs of the Board of the Quality Healthcare and Patient Safety Authority. It establishes the procedures and governance framework guiding the Board's meetings, decision-making, and general administration. It outlines provisions on the convening and frequency of Board meetings, quorum requirements, and voting procedures.

55. The First Schedule stipulates that the Chairperson shall preside over meetings, and in their absence, members shall elect one among themselves to chair. Decisions of the Board are to be made by a majority of the members present and voting.
56. The Schedule also provides for the keeping of proper minutes and records of all Board proceedings, the establishment of committees to support the execution of its functions, and the delegation of functions to committees or officers. Provisions are also included on conflict-of-interest declarations and confidentiality obligations. It thus operationalizes the governance of the Authority by setting clear administrative and procedural rules that promote transparency, accountability, and efficiency in the conduct of Board business.
57. The **Second Schedule** provides for consequential amendments to various statutes, including the Health Act (Cap. 241), the Public Health Act (Cap. 242), the Pharmacy and Poisons Act (Cap. 244), and the Acts establishing the respective health regulatory bodies, in order to ensure consistency and alignment with the provisions of the Quality Healthcare and Patient Safety Bill, 2025 regarding the regulation of health facilities, the delivery of quality healthcare services, and the promotion and protection of patient safety.

CHAPTER TWO

2.0 STAKEHOLDER SUBMISSIONS

2.1. Introduction

58. The Committee received written submissions from one hundred and eighty (180) stakeholders. Twenty-three (23) of these submissions were by institutions and the remaining from individuals. Of the individual submissions, over one hundred (100) submissions were a duplication of the submissions by the Kenya Union of Medical Laboratory Union and Association of Medical Laboratory Officers. This Chapter analyses the submissions thematically, following the Bill's structure as provided for in Chapter One of this report.
59. Two broad positions emerged from the submissions received. A significant number of stakeholders, including the Ministry of Health, the Council of Governors, the Rural and Urban Private Hospitals Association of Kenya (RUPHA), and several individual experts, supported the retention of the Bill, subject to the incorporation of specific amendments. The proposed amendments principally sought to address concerns relating to regulatory duplication, the constitutional framework of devolution, protection of the health workforce and the inclusion of patient-centred safeguards.
60. The majority of these stakeholders submitted that the Bill would strengthen the health-care system by enhancing regulatory oversight, improving standards of care and promoting compliance by health facilities with applicable legal and professional requirements. They further observed that these functions would be undertaken under the oversight of the proposed Quality Healthcare and Patient Safety Authority (QHPSA).
61. The stakeholders justified the proposed measures on account of the reported increase in health facilities operated by unqualified persons, the proliferation of unlicensed facilities in which medical procedures are allegedly undertaken by unqualified practitioners, incidences of medical negligence, and inadequate infrastructure in a number of health facilities. They further noted that these concerns are compounded by the absence of uniform national standards for the regulation and delivery of health-care services.
62. Another section of stakeholders, including the Kenya Union of Clinical Officers (KUCO), the Kenya National Union of Medical Laboratory Officers (KNUMLO) and several individual stakeholders associated with those organizations, urged the Senate to withdraw the Bill in its entirety.

63. They submitted that the Bill substantially duplicates the provisions of the Health Act, 2017; was developed without adequate consultation with key implementers; and does not sufficiently address the underlying constraints affecting the quality of health-care services, including inadequate financing, staffing shortages, and deficient infrastructure.
64. In the alternative, the stakeholders proposed the inclusion of savings clauses and mutual-recognition frameworks to preserve the mandates of professional regulatory bodies in relation to the registration, licensing, discipline, and regulation of the scope of practice of health-care professionals. They submitted that such provisions would minimize duplication and potential conflict between the functions of the proposed Quality Healthcare and Patient Safety Authority and those of the respective health-profession regulatory bodies.

2.2. Stakeholder Submissions

65. On definitions of the Bill, the Kenya Medical Association (KMA), the Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) and the Pharmaceutical Society of Kenya (PSK) proposed the insertion of, or refinement to, definitions of certain terms, including “medical aesthetic procedure”, “patient-centered care”, and “adverse event”, in order to enhance clarity and eliminate ambiguity in the application of the Bill.
66. With regard to the guiding principles set out under clause 4, the Consumer Federation of Kenya (COFPAK), KELIN, KMA and the Council of Governors (CoG) proposed the inclusion of patient engagement, transparency, adequacy of the health workforce and continuity of care at all levels of health-care delivery as express guiding principles under the Bill.
67. On the roles of the Cabinet Secretary and county governments, Council of Governors (CoG) sought a dedicated “County Quality Governance” framework recognizing devolved responsibility for service delivery, while Kenya Union of Clinical Officers (KUCO) and Dr Ghalib Moseti Abdillahi called for mandatory consultation with counties and professional regulators before national standards, facility closures or performance ratings affecting devolved facilities are imposed.
68. Stakeholders generally welcomed the patient-rights framework proposed under the Bill, while calling for measures to strengthen its enforceability and practical application. The IDinsight Dignity Initiative proposed the definition of “patient satisfaction”, the express incorporation of informed-consent requirements and the

guarantee of a patient's right to be accompanied by a person of his or her choice while receiving care. The organization cited survey findings indicating that a substantial proportion of Kenyans had experienced violations of their right to be treated with dignity.

69. In relation to the right to receive care from a qualified health-care professional, KMA proposed that a health-care provider should, in addition to being duly qualified and licensed, be a member in good standing of the relevant recognized professional association. COFPAK and KMA further proposed the establishment of accessible and effective redress mechanisms, rather than reliance solely on patient charters and regulations to be developed under the Act.
70. The Pharmaceutical Society of Kenya (PSK) recommended the inclusion of an express right to pharmaceutical care. KELIN further proposed that the Patients' Rights Charter to be developed under the Act should conform to the World Health Organization (WHO) Patient Safety Rights Charter.
71. With respect to the determination of scope of practice under clause 18 of the Bill, a significant number of stakeholders, including the Kenya Medical Association (KMA), the Kenya National Union of Medical Laboratory Officers (KNUMLO), the Kenya Union of Nutritionists and Dieticians (KUNAD), the Biomedical Clinical Medicine Graduates Association (BCMGA), the Kenya Union of Clinical Officers (KUCO), the Kenya Environmental Health and Public Health Practitioners Union (KEHPHPU), and Dr. Ghalib Moseti Abdillahi, objected to the proposed vesting of this function in the Cabinet Secretary upon the recommendation of the Director-General.
72. The stakeholders submitted that the proposed arrangement may give rise to an actual or perceived conflict of interest and could encroach upon the statutory mandates of the respective professional regulatory bodies. They therefore proposed that the determination and regulation of the scope of practice of health-care professionals be vested in the relevant professional regulatory body.
73. On penalties under clause 18(2), KUCO, KNUMLO, Chacha Omahe and the Health Unions Caucus argued the ten-million-shilling fine is punitive and would discourage error reporting, proposing a graduated, "just culture" enforcement model beginning with corrective orders. They proposed a reduction in the penalty to ensure the same is not punitive.

74. On professional indemnity highlighted in clause 24, PSK and Dr. Gahlib Moseti, urged an amendment to provide that a health facility shall obtain a various liability cover for its employees, interns and trainees without prejudice to individual professional cover. On clause 25, Kennedy Kinyua proposed a replacement of clause 25 (b) with a duty for patients to participate in care and communicate decisions honestly without limiting the right to refuse or withdraw consent. On clause 25 (f) KMA proposed that where a patient refuses to accept or implement recommended treatment, the clause should provide that informed refusal should be consistent with section 8 of the Health Act.
75. On the functions of the Quality Healthcare and Patient Safety Authority provided under clause 27 of the Bill, COFPAK, PSK, KEHPHU, Dr Ghalib Moseti Abdillahi and George Okoth Osimbo proposed express savings provisions confirming the Authority regulates health institutional systems rather than individual professionals and that its exercise of functions is without prejudice to existing regulators statutory mandates, to forestall the “partial absorption” of professional regulation feared by several health professional bodies.
76. Clause 28 on the powers of the Board also attracted a number of submissions from stakeholders. RUPHA proposed a deletion of clause 28 (2) (f) which touches on the powers to the Board to levy or charge fees for the services rendered by the Authority. They recommended in the alternative leaving the question of fees to regulations under clause 93 of the Bill. This position was also supported by the Kenya Medical Association (KMA). KMA also sought an exclusion of facilities licensed under the Act from the single business permit or trade license by county governments.
77. Clause 29 of the Bill touches on the composition of the Board of the Quality Healthcare and Patient Safety Authority. On this provision, stakeholders sought named or reserved seats for their respective institutions. KMA, PSK, KNUPT and the Lab Medicine Society of Kenya (LMSK), KMLTTB sought their representation to the Board. KUCO urged for county representation and Youth Champions for SDGs championed for youth representation. COFPAK and KELIN championed for patient or public-interest representatives.
78. This part also attracted a number of submissions, KMA urged the separation of licensing from accreditation and permit the Quality Healthcare and Patient Safety Authority to recognize credible independent or international accreditation bodies such as KENAS rather than vesting accreditation entirely to the authority. COG also championed for recognition of existing accreditation programmes.

Pharm access urged the committee to assign the accreditation function to an independent accreditation body distinct from the Authority.

79. The Pharmaceutical Society of Kenya (PSK) on their part, urged the Committee to include a new provision providing that a pharmacy premise registered and licensed under the Pharmacy and Poisons Act, shall not require a duplicate operational registration under this Act.
80. On suspension, revocation and closure of facilities, KMA, George Okoth Osimbo and Dr Ghalib Moseti Abdillahi sought proportionality safeguards, including prior written notice, a defined opportunity to remedy minor breaches, patient-transfer and continuity-of-care plans before closure. They also urged that the appeal timelines should be consistent with the fair administrative action under Article 47 of the Constitution.
81. Inspections and investigation of health facilities is provided for under clauses 72 to 82 of the Bill. The main concern, raised by KMA, PSK, the Lab Medicine Society of Kenya and several laboratory professionals, was that inspection of specialised clinical services such as laboratories, pharmacies and radiology should be conducted jointly with, or in the presence of, the relevant statutory regulator, since generalist inspectors may lack the technical competence to assess specialized practice. KEHPHU proposed a collective Inspectorate Unit rather than individual inspectors, to reduce the risk of bias.
82. Kennedy Kinyua and Dr Geoffrey Maiyoh sought minimum inspector qualifications in the Act itself, a defined proportion of unannounced inspections, warrant requirements for non-consensual searches, and rapid review of emergency suspension orders. RUPHA proposed that a review or appeal against suspension or revocation operate as an automatic stay unless the Authority certifies an immediate risk to patient safety.
83. Clauses 83 to 86 of the Bill deals with the establishment, membership, jurisdiction and functions of the Healthcare Tribunal. Stakeholders raised concerns about the Tribunal's composition and jurisdiction. KMA urged the distribution of the four healthcare professionals' positions under clause 83 (2) (c) to be distributed across recognized health disciplines such as medicine, dentistry, nursing and pharmacy. COFPAK on their part championed for a person representing patient interests to the tribunal.

84. The Health Union Caucus urged that the power to appoint members of the tribunal be undertaken by the Cabinet Secretary for Health as opposed to the judicial service commission to ensure that the authority over the management of health matters is retained with the Cabinet Secretary for Health. They also request that the chairpersons of the regulatory bodies within the health sector be members of the Tribunal. They also propose the reduction of the number of advocate members of the tribunal from three (3) to one (1). KEHPPU sought guaranteed seats for healthcare professionals to the membership of the Tribunal. Pharmacare sought the addition of a person with expertise in pharmaceutical or medicine safety expertise to be a member of the Tribunal.
85. With regard to the jurisdiction of the Tribunal, Kenya Medical Association (KMA) sought to limit the appellate jurisdiction of the Tribunal over decisions of the Authority made under this Act. They urged the deletion of the words “any relevant regulatory body” so that appeals against the decisions of professional bodies lie to the High Court. Rewan consultancy submitted that the Tribunal should only handle disputes relating to quality of care and patient safety while referring professional misconduct cases to relevant professional councils.
86. RUPHA urged the committee to restore the wording of clauses 84 (1) and 84 (3) of the Bill as they appeared in the original Bill introduced in the National Assembly. They championed for the Healthcare Tribunal to take over the operations of the SHA tribunal established under section 44 of the Social Health Insurance Act.
87. Clauses 87 to 92 of the Bill provides for the financial provisions. IDinsight Dignity Initiative and KMA proposed a ring-fenced funding floor for the Authority’s core patient-safety functions and transitional support for regulators losing inspection-fee revenue.
88. IDinsight Dignity Initiative, further called for the deletion of clause 92 (3) (a) touching on the contents of the report submitted by the Cabinet Secretary to parliament. This provision requires the cabinet secretary to submit a report containing data on quality improvement, patient outcomes, patient satisfaction and health system performance. They propose replacing the provision with a clause that requires the cabinet secretary to provide data on quality improvement, patient outcomes, patient satisfaction, and health system performance disaggregated by county and by sex, age, disability, and socio-economic status.

89. Clause 93 of the Bill provides for making of regulations by the Cabinet Secretary. RUPHA emphasized on the need for public participation by the regulations made by the Cabinet Secretary. George Okoth Osimbo proposed that the making of regulations by the Cabinet Secretary should be done in consultations with relevant health professional regulatory bodies, county governments, and other relevant stakeholders.
90. The pharmaceutical Society of Kenya urged the committee to replace the powers of the CS to make regulations on “standards of pharmacies” with “the general quality of care and patient safety standards applicable to pharmacy services, developed in consultation and concurrence with the pharmacy and poisons Board, excluding professional practice, scope of practice, licensing of pharmacy premises and regulation of health products.
91. LMSK also urged the replacement of clause 93 (2) (g) referring to “standards of medical laboratories” with “standards of medical laboratories made in consultation with the Kenya Medical Laboratory Technicians and Technologists Board.” KUCO called for the insertion of an express provision requiring that the regulations shall not vary a statutory professional scope, transfer of county function, or derogate from another Act unless expressly authorized by the primary legislation.
92. On clause 96 with addresses confidentiality concerns, Dr Ghalib Moseti Abdillahi, KMA and Kennedy Kinyua sought express alignment with the Data Protection Act, 2019.
93. On offences and penalties under clauses 97 and 98 of the Bill, KMA urged the application of corresponding and proportionate reduction to the penalties under clauses 48, 55 and 98 and introduce tiered penalties by facility categorization. Dr. Ghalib Abdillahi recommended lowering of the general penalty and require the courts to have regard to the gravity of the contravention whether it was deliberate, whether patients were exposed to harm and the category and resources of the facility.
94. On clause 99, RUPHA submitted that the committee amends the clause to include a provision requiring that a certificate of registration, license or accreditation held under any written law immediately before the commencement of this Act shall remain valid until the Authority determines an application made under this Act in respect of that health facility and that no offence shall arise in respect of the health facility whose application is pending determination by the Authority.

95. The Health Union Caucus also propose that all health facilities registered before the commencement of this law should be deemed to have been registered under the Act.
96. KMA and KUCO suggested that before transfer of staff to various professional bodies to the Authority, under clause 99 (4), a joint capacity assessment between the cabinet secretary and the affected regulatory bodies, a defined consultation process and protection of affected staff's accrued terms and benefits must be adhered.
97. LMSK, proposed deletion of clauses 99 and 100 and instead proposed the insertion of a saving clause preserving all existing registrations, licenses, accreditations and ongoing disciplinary proceedings under Cap 253A.
98. On clause 100, which provides for the amendment of various Acts of parliament in accordance with the second schedule, the healthcare professional association bodies urged that the amendments should be done in a manner that preserves the professional regulation of healthcare professionals to the respective health professional bodies to ensure that there is clarity of mandate between the Quality Healthcare and Patient Safety Authority and the respective health professional regulatory bodies.
99. Beyond the Bill's existing Parts, stakeholders proposed the inclusion of healthcare worker rights and safety given the Bill's silence on the working conditions of the providers it regulates, artificial intelligence, telemedicine and digital health standards. They also proposed for the express inclusion of protection against denial or delay of emergency treatment on financial grounds.
100. A matrix of stakeholder submissions is attached to this report as *Annex 5*.

CHAPTER THREE

COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

3.1. Committee Observations

101. Having considered the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bills No. 41 of 2025) and submissions from stakeholders, the Committee made the following observations —

- (1) that a majority of the 180 stakeholders, including the Ministry of Health, Council of Governors and RUPHA supported retention of the Bill. They affirmed that the Quality Healthcare and Patient Safety Authority will strengthen oversight, raise health standards and curb the proliferation of unlicensed facilities and unqualified practitioners undermining patient safety nationally;
- (2) that Health facilities are currently licensed under fragmented professional statutes such as the Medical Practitioners and Dentists Act, the Clinical Officers Act and the Nurses and Midwives Act, each Council regulating premises incidental to its own profession. Quality is governed only by non-binding policy; no statute defines measurable quality standards, provides for facility accreditation, mandates adverse event reporting or grants patients enforceable rights against a health facility. The Committee observes that the Bill cures this legislative gap, giving effect to Article 43(1)(a) of the Constitution and advancing the realisation of Universal Health Coverage;
- (3) that clause 27 of the Bill confines the Authority's functions to registration, licensing, accreditation and inspection of health facilities, which addresses the stakeholder concern that it would absorb professional regulation. The Second Schedule reinforces this by amending professional statutes to preserve professional bodies' mandate over training, registration, licensing, scope of practice and discipline of healthcare professionals and therefore ensuring the regulation of health facilities and health professionals is distinct;
- (4) that concerns were raised by stakeholders about the potential conflict of mandate between the Quality Healthcare and Patient Safety Authority and the Kenya Health Professions Oversight Authority (KHPOA) established under the Health Act. The Committee notes that the mandate of the Quality Healthcare and Patient Safety Authority under clause 27 is clear and limited

to regulation of healthcare facilities. Further, the Second Schedule already amends section 48 of the Health Act to confine KHPOA to regulation of healthcare professionals. The two bodies therefore operate on separate subjects, and no duplication arises;

- (5) that a number of stakeholders also raised concerns about whether the Healthcare Tribunal established under this Bill will take away the adjudicatory functions of other bodies within the health sector. Clause 84 (1) of the Bill however limits the jurisdiction of the Tribunal to matters under this Bill. The Committee notes that while clause 84 (4) of the Bill gives appellate powers to the Tribunal over decisions of the Authority, the use of the words “other relevant regulatory Agencies within the health sector” may be interpreted to mean the Tribunal has powers beyond the scope of this law and therefore the need for an amendment;
- (6) that Stakeholders raised a concern that the Healthcare Tribunal may displace the adjudicatory functions of other health sector bodies and particularly, matters touching on the discipline of health professionals. The Committee notes that clause 84(1) limits the Tribunal’s jurisdiction to matters under this Bill. However, the phrase “other relevant regulatory Agencies within the health sector” in clause 84(4) may be read as extending appellate powers beyond this law’s scope, and therefore need for an amendment; and
- (7) The Committee affirmed that patients deserve quality healthcare and safety and must therefore play an active role in matters touching on the quality of service rendered to them by health facilities. This fosters active participation and shared decision-making between the recipient of care and healthcare providers, reinforcing the Bill’s patient-centered approach to realizing Article 43(1)(a) of the Constitution and therefore the need for an amendment to the Bill.

3.2. Committee Recommendations

- 102. Having considered the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025) and the memoranda received from stakeholders, the Committee recommends that the Senate passes the Bill with the proposed amendments.

14th September, 2026

The Clerk of the Senate,
Parliament Buildings.

NAIROBI.

**RE: COMMITTEE STAGE AMENDMENTS TO THE QUALITY
HEALTHCARE AND PATIENT SAFETY BILL, 2025 (NATIONAL
ASSEMBLY BILLS NO. 41 OF 2025)**

NOTICE is given that the Chairperson of the Senate Standing Committee on Health intends to move the following amendments to the Quality Healthcare and Patient Safety Bill, 2025 (National Assembly Bill No. 41 of 2025), at the Committee Stage –

CLAUSE 4

THAT clause 4 of the Bill be amended by inserting the following new paragraphs immediately after paragraph (b) –

(ba) promotion of patient engagement and empowerment;

(bb) promotion of continuous and integrated quality healthcare across all levels of care, including community health services, primary healthcare, referral services, rehabilitative care and palliative care;

CLAUSE 5

THAT clause 5 of the Bill be amended in paragraph (c) (iv) by inserting the words “and patient’s” immediately after the words “healthcare provider’s.”

CLAUSE 6

THAT clause 6 of the Bill be amended —

(a) in paragraph (f) by inserting the words “and patient safety” immediately after the words “quality improvement; and

(b) by inserting the following new paragraph immediately after paragraph (g) –

(ga) ensure health facilities establish and maintain an appropriate clinical governance framework to ensure continuous improvement in the quality, safety, effectiveness and patient-centeredness of healthcare services;

CLAUSE 29

THAT clause 29 of the Bill be amended in subsection (1) by deleting paragraph (h) and substituting therefor the following —

(h) one person appointed by the Cabinet Secretary from a nationally recognized patient safety advocacy organization to represent the interests of the patients;

CLAUSE 83

THAT clause 83 of the Bill be amended in subsection (2) —

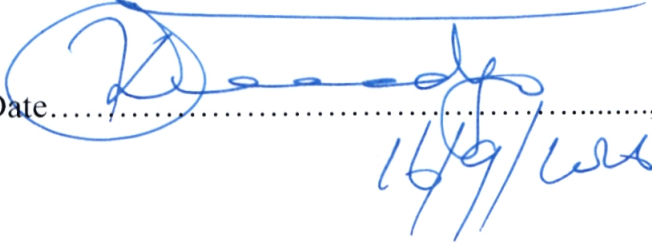
(a) paragraph (d) by deleting the word “three” appearing immediately before the words “other persons” and substituting therefor the word “two”;

(b) by inserting the following new paragraph immediately after paragraph (d) —
(da) one member with demonstrable experience in quality improvement and patient safety advocacy, who shall be appointed by the Judicial Service Commission.

CLAUSE 84

THAT clause 84 of the Bill be amended by deleting subclause (4) and substituting therefor the following new subclause —

(4) The Tribunal shall have appellate jurisdiction over the decisions of the Authority and in exercise of its functions, may refer any matter back to the Authority for reconsideration.

Date....., 2026.

16/9/2026

Senator Jackson Mandago EGH, M.P.
Chairperson, Standing Committee on Health.