

NATIONAL EXECUTIVE

KMA CENTRE, CHYULU ROAD, P.O. BOX 48502 - 00100 GPO, NAIROBI-KENYA

Mobile: 0722-275695

Email: nec@kma.co.ke Website: www.kma.co.ke

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Kenya Medical Association Input On The Quality Healthcare And Patient Safety Bill, 2025

The Kenya Medical Association (KMA) is the umbrella professional association for doctors in Kenya. Established in 1968, KMA is mandated to champion the welfare of doctors and advocate for quality healthcare in the country. As a representative body for medical professionals, KMA is dedicated to ensuring the highest standards of healthcare delivery and advocating for necessary reforms within the healthcare sector.

The Kenya Medical Association (KMA) recognises the introduction of the Quality Healthcare and Patient Safety Bill, 2025. We note the critical need for a robust legal framework to standardize healthcare quality, enhance patient safety, and protect patient rights across Kenya. We broadly support the objects of this act outlined in Clause 3 and the principles for implementation in Clause 4, which align with our commitment to ethical, equitable, and evidence-based medical practice.

Kenya Medical Association (KMA) supports the Bill's provisions on: Patient Rights (Part II) Clauses 7–18 comprehensively defining patient rights, including informed consent (Clause 12), dignity (Clause 17), and access to qualified professionals (Clause 9) elements that represent essential standards in patient care which require clear operational guidelines and consistent enforcement. The inclusion of quality assurance mechanisms, (Clauses 19–24) rightly mandating safety protocols, risk management, and continuous professional development, reflects an attempt to address existing systemic gaps. Considerations for standardized regulation through the establishment of a dedicated Authority (Clause 27) for oversight, accreditation, and enforcement is necessary for national coherence.

The following table outlines KMA's technical assessment of critical clauses requiring revision:

| Regulation / Clause | Issue of Concern | Justification | Recommendation |
|-------------------------------------|--|---|---|
| Part II : Patient Rights and Safety | | | |
| Clause 9 | Absence of professional association membership requirement for healthcare professionals. | Global practice ensures all practicing professionals are members of a professional association. This strengthens self | Add: "9(b) Healthcare professionals who are members in good standing of a registered professional association." |



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| | | regulation, sets standards for practice. | |
| Clause 21 | Need for implementation support mechanisms. | To operationalize evidence-based practice. | Develop accessible national clinical guidelines and resources to operationalize evidence-based practice. |
| Clause 25 | Professional Indemnity with unclear interaction with existing malpractice frameworks. | Requires clarity on interaction with existing medical malpractice insurance frameworks. | Explicitly state: "This clause supplements but does not replace current indemnity arrangements." |
| Clause 26 | Risk of misinterpreting patient duties to deny care. | While patient responsibilities are valid, this must not be used to deny care or undermine the primary duty of providers. | Revise wording to ensure collaborative patient-provider relationships without compromising access. |
| Part III : Governance & Administration of Quality Healthcare | | | |
| Clause 30 (f)(i) – Board of Directors | Exclusion of practicing clinicians and frontline health from Board representation. | Excludes voices of those directly impacted by decisions; undermines professional autonomy. | Amend Clause 30 to mandate seats for KMA, NNAK and COC |
| Clause 31 1(e) – Qualification of Chairperson | Omission of professional body membership requirement for Chairperson. | Membership of good standing in professional Association demonstrates active practice. | Add: "Membership in good standing of a relevant professional association." addition to the relevant regulatory body. |



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| Clause 37 – CEO Qualifications | Lack of clinical leadership experience in quality and safety requirement for CEO. | Risk of appointing non-clinicians without adequate expertise in healthcare systems. | Specify mandatory clinical leadership experience in healthcare quality management. |
|--|--|--|--|
| Р | art IV : Registration, Licensi | ng And Accreditation of He | alth Facilities |
| Clauses 44–57 (Licensing) & 58–66 (Accreditation) | Duplication with existing regulations (Health Act CAP 242, KMPDC functions) | Risks bureaucracy, redundant inspections, conflicting mandates, and overburdening facilities. | Ensure seamless integration with current systems; avoid duplicating roles and streamline regulatory processes. |
| Clauses 46, 51, 60 | Disproportionate compliance burden on small/rural facilities. | These facilities may lack technical and financial capacity, risking exclusion or closure. | Introduce phased implementation, financial and technical support, and apply differentiated standards based on facility level (Clause 54). |
| Clause 60 – Combined Licensing & Accreditation | Critical Conflict from merging enforcement (licensing) with quality improvement (accreditation). | Risk of: - Coercive accreditation - Undermining voluntary improvement - Ignoring global best practices | Legally separate licensing and accreditation functions that are anchored in law. Authorize collaboration with non-governmental accreditation bodies. |
| Clauses 68–69 – Quality Scoring | Non-transparent quality scoring methodology. Absence of risk adjustment. | Public rating systems must balance transparency with avoiding unintended consequences (e.g., undermining struggling facilities). | Focus ratings on driving improvement; ensure due process before public disclosure of negative ratings. Require public consultation on criteria and establish appeal mechanisms. |



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| Part V : Inspections, Investigations And Enforcement | | | |
|--|--|---|--|
| Clause 77 | Risk of non-clinical inspectors assessing clinical safety. | Inspectors must possess relevant clinical expertise for the facilities they assess. | Mandate minimum clinical qualifications and ongoing training for inspectors. |
| Clause 68-70 | Unintended consequences of public ratings ("naming/shaming"). | Public rating systems must balance transparency with avoiding unintended consequences (e.g., undermining struggling facilities). | Focus ratings on driving improvement; ensure due process before public disclosure of negative ratings. Withhold public ratings until completion of corrective action; prioritize improvement over punishment. |
| | Part VI: Th | ne Healthcare Tribunal | |
| Clause 85 | Tribunal Composition Critical Gaps: - Exclusion of practicing clinicians - No collaboration mechanism with KMPDC - Risk of fragmented complaint resolution | The Tribunal adjudicating disputes must include senior practicing clinicians. We oppose the restriction of health service providers as members of the tribunal. KMPDC has been handling disciplinary cases for hospital and | Amend to require: - Significant clinical representation - Mandatory inclusion of professional regulatory bodies in dispute resolution |



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| | | supported by professional associations, enabling efficient resolution of patient complaints. The proposed tribunal does not clearly define how it will collaborate with the professional regulatory bodies to resolve complaints and avoid patients reporting to several institutions. | | |
|------------|--|--|--|--|
| | Part VI—The Healthcare Tribunal | | | |
| Clause 88 | Authority Funding (The current professional regulatory bodies including KMPDC have faced significant funding gaps that impact their ability to deliver their mandate to inspect facilities to ensure compliance.) | Sustainable funding is critical for the Authority's effectiveness. | Ensure ring-fenced funding in the national budget, potentially supplemented by reasonable, non-punitive fees scaled to facility size/type and ensure parallel support for legacy regulators. | |
| Clause 101 | Inadequate transition planning. | A realistic and adequately resourced transition period is essential. | Specify a minimum transition period (e.g., 18-24 months) with clear technical/financial support mechanisms. | |



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Kenya Medical Association stands ready to collaborate with the Ministry of Health and the proposed regulatory Authority in the development of detailed regulations (Clause 94) and clinical guidelines. KMA further offers its technical expertise to support the work of relevant Board committees (Clause 34) and the training of inspectors. In addition, KMA is committed to contributing to the successful implementation of quality improvement initiatives (Clause 67) and professional training programs (Clause 24), recognising these as essential components in strengthening healthcare delivery systems.

In conclusion, the Quality Healthcare and Patient Safety Bill, 2025 presents a vital opportunity to transform Kenya's healthcare landscape and advance healthcare standards in Kenya. While KMA supports the Bill's overarching objectives, it urges careful attention to key concerns, including the need for inclusive governance structures, avoidance of bureaucratic inefficiencies, protection of under-resourced facilities, and the integration of clinical expertise within oversight bodies. Addressing these key issues will ensure that the resulting framework is effective, equitable, and responsive to the needs of all stakeholders, ultimately promoting safer and higher-quality care for all Kenyans.

We particularly recommend that the bill undergo further critical deliberation, with particular attention given to addressing the significant concerns raised. Specifically, we urge that the separation of licensing and accreditation be carefully considered prior to its progression in Parliament.

Dr. Diana Marion

Secretary General, Kenya Medical Association