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The New Health Bill Could Hurt, Not Help: Why Experts are Worried About Patient Safety and Access

A proposed law, meant to improve the safety and quality of health services in Kenya could do more harm than good. While it promises to reduce fraud and improve care, the Quality Healthcare and Patient Safety Bill, 2025 risks centralizing too much power, creating confusion among regulators, and making it harder for patients and providers—especially in rural counties—to access healthcare and justice.

What may be wrong with the Contents of the Bill

On 29th July 2025, the Kenya Cabinet approved the Bill for Parliament's consideration. But a closer look reveals troubling gaps in how it will be enforced, who it will affect, and whether it upholds the Constitution. Despite its ambitious framing to curb fraud and malpractice, the **"Quality HealthCare and Patient Safety Bill"** does not clearly demonstrate how it will achieve measurable improvements in the quality of care or patient safety.

While the Bill outlines extensive responsibilities for health facilities such as mandatory licensing and registration, infection prevention control, annual safety audits, reporting of adverse events, and implementation of quality improvement programs there is little clarity on **enforcement**, **financing**, or **capacity building** to support implementation across Kenya's diverse devolved health system.

Unconstitutionality of contents of the Bill

The proposed establishment of the **Quality Healthcare and Patient Safety Authority (QHPSA)** under the Quality Healthcare and Patient Safety Bill, 2025, also raises serious concerns regarding regulatory overreach and duplication of mandates. Health services are managed by counties, not just the national government. Giving all the power to one Authority in Nairobi ignores this and violates the rules of devolution and fair decision-making. The proposed Authority is granted wide ranging powers including licensing and accreditation of healthcare facilities and professionals, inspection and enforcement of quality standards, imposition of penalties, oversight of professional scope of practice, operation of a central tribunal, and issuance of policy directives.

How contents of the Bill affect you- patients and health workers

This unprecedented consolidation of functions currently performed by independent professional regulatory councils (such as the *Clinical Officers Council, Nursing Council of Kenya, Kenya Medical Practitioners and Dentists Council, Pharmacy and Poisons Board, and Kenya Medical Laboratory Technicians and Technologists Board)*, the County Governments under devolved health mandates, and the Kenya Health Professions Oversight Authority (KHPOA), poses multiple risks including inter-alia:

a. Undermines professional self-regulation: By usurping functions such as determining scope of practice, licensing, and disciplinary processes, QHPSA threatens the legal autonomy of professional bodies established under specific Acts of Parliament.
b. Contradicts the Constitution of Kenya, 2010: Health is a devolved function (Fourth Schedule), and this centralization violates the principles of devolution (Articles 6(2), 10, 174, and 187 of the Constitution of Kenya, 2010), as well as fair administrative action (Article 47 of the Constitution of Kenya, 2010).
c. Creates duplication and confusion: With overlapping mandates between QHPSA, KHPOA, Ministry of Health (MOH) directorates, and existing regulatory councils, the implementation and compliance landscape become fragmented, leading to administrative confusion and legal contestation.
d. Compromises efficiency and specialization: Each health profession requires context-specific regulation informed by practitioners with domain expertise. Centralizing such nuanced processes under a general authority risk compromising both quality and responsiveness. The Bill seeks to establish a unified Healthcare Tribunal, scraping off other existing specialized mechanisms such as the HIV Tribunal, that would oversee all disputes involving patients, healthcare professionals and providers. This will be detrimental to the lived realities of key affected populations who face additional vulnerabilities and whose specific needs might not be addressed in a general tribunal.
e. Lack of a clear accountability framework: While the bill mentions several compliance requirements ranging from evidence based clinical guidelines and competency-based staffing to data submission and inspection compliance, the Bill still lacks a clear accountability framework, funding provisions, or national baseline standards to define what quality and safety mean in the Kenyan context. Penalties ranging from KES 1 million to 50 million, though intended to deter malpractice, may instead discourage smaller health providers, and create additional barriers to access to healthcare services, especially in low resource counties.
f. Disconnect between title and substance: The title "Patient Safety" suggests a people centered, rights-based framework focused on reducing harm, improving outcomes, and embedding a culture of safety across health systems. However, the Bill focuses more on structural control and compliance than on empowering patients, supporting healthcare workers, or embedding learning systems like clinical audits, peer reviews, and whistleblower protections. The risk is that the Bill becomes administrative and punitive, rather than transformational and preventive.
g. Global best practices: The UK and USA approach: In the United States, professional regulation is decentralized but cadre specific, ensuring each profession is held to appropriate standards. Medical doctors are licensed by the State Medical Boards, nurses by State Boards of Nursing, and PAs by the National Commission on Certification of Physician Assistants (NCCPA). Other cadres such as pharmacists, lab technicians, and allied health professionals are similarly regulated by distinct bodies, with coordination through national associations. This model ensures clear professional accountability, scope specific standards, and localized oversight.

What other countries do differently

Other countries also regulate healthcare- but they do it in a way that protects professional independence and patient safety. In the United Kingdom, regulation is more centralized but remains professionally segmented. The General Medical Council (GMC) oversees doctors; the Nursing and Midwifery Council (NMC) governs nurses and midwives; the General Pharmaceutical Council (GPhC) oversees pharmacists; and the Health and Care Professions Council (HCPC) covers more than 15 allied health cadres. These bodies operate independently of the government, ensuring professional autonomy, transparency, and sectoral expertise in regulation.

Both systems separate licensing, inspection, tribunal, and quality assurance functions, ensuring that oversight does not become concentrated or politicized. Kenya's proposed model under QHPSA, however, bundles all these functions under a single authority, which is contrary to these best practices.

Specific Objections to The Quality Healthcare and Patient Safety Bill, 2025

1. Central regulation of medical professions

PART	CLAUSE(S)	COMMENT	PROPOSED CHANGE	RELEVANT EXISTING LAW
Preliminary	Clause 2 (Definitions)	The Bill empowers the Director General to determine the "scope of practice" across professions, which overrides the statutory powers of independent health professional regulatory councils.	Amend to state: *"Scope of practice shall be determined by the respective regulatory councils established by law."*	Cap 253E (Clinical Officers), Cap 257 (Nurses), Cap 253A (Lab Technologists), Cap 244 (Pharmacists), Cap 253 (Doctors & Dentists)
Quality Administration	Clause 15	Establishes a central National Quality Healthcare Unit, which duplicates roles of regulatory bodies and the Ministry of Health's Quality Directorate.	Redefine the Unit as an **advisory body** that coordinates quality assurance without usurping regulatory councils' mandates.	Cap 253E Sec 4(m); MOH Quality Directorate; Cap 257 Sec 5
Licensing and Accreditation	Clauses 28, 44–61	The Authority assumes powers to license, accredit, and approve training of all healthcare providers—functions already vested in existing regulatory bodies.	Limit the Authority's role to coordination and oversight; licensing and training accreditation should remain with the councils.	Cap 253E Sec 6; Cap 257 Sec 9; Cap 253A Sec 6; Cap 244 Sec 3A
Inspections and Enforcement	Clauses 19, 21, 67	Centralizes inspection and enforcement, with penalties imposed outside council frameworks, bypassing professional disciplinary procedures.	Inspections should be **coordinated with councils**, and enforcement actions aligned with each council's disciplinary mechanisms.	Cap 253E Part IV; Cap 257 Sec 16; Fair Administrative Action Act

Tribunal	Clauses 60–70, 86	The Tribunal established may override professional boards' decisions, creating jurisdictional conflict and undermining self-regulation.	Amend to ensure the Tribunal **only hears appeals** after exhaustion of existing council mechanisms.	Cap 253E Sec 15; Cap 257 Sec 14; Cap 253A Sec 11
Schedules	Schedule 1 (Board Composition)	Key professional councils are excluded from the Board, despite their statutory mandate over training, ethics, and licensing.	Include representatives from: Clinical Officers Council, Nursing Council, MLTTB, Pharmacy and Poisons Board, Kenya Medical Practitioners and Dentists Council.	Cap 253E, Cap 257, Cap 253A, Cap 244, Cap 253

2. HIV/AIDS, SHIF, and the proposed Healthcare Tribunal

CLAUSE / PART	COMMENT	PROPOSED CHANGE	REASON FOR PROPOSED CHANGE
Part VI – The Healthcare Tribunal	The Bill replaces the HIV/AIDS Tribunal and SHIF Dispute Tribunal with a general Healthcare Tribunal, removing specialized tribunals.	Maintain the HIV/AIDS Tribunal and the SHIF Dispute Tribunal as separate entities under their respective parent Acts. Limit the new Healthcare Tribunal to specific mandates e.g., disputes on quality assurance, accreditation, licensing, and general care standards not covered elsewhere.	The HIV/AIDS Tribunal has specialized expertise in handling stigma, confidentiality, ART access, and discrimination cases. Replacing it may compromise the quality and sensitivity of adjudication. SHIF Tribunal specializes in financing disputes. A single general tribunal will dilute expertise, delay justice, and burden vulnerable populations, especially PLHIV.
Part VI – Composition of Tribunal	There is a conflict in appointment processes: the HIV/AIDS Tribunal is appointed by the Attorney General, while the SHIF Tribunal involves Presidential and JSC appointments.	Avoid merging tribunals with incompatible appointment structures. Retain separate tribunals and harmonize their mandates through coordination mechanisms rather than structural fusion.	Merging tribunals with different legal foundations and appointment mandates may result in procedural inconsistencies, legal challenges, and unclear lines of authority. Professionally designed coexistence of tribunals preserves both expertise and legal coherence.
Part VI – Jurisdiction of Tribunal	The Tribunal as proposed usurps High Court jurisdiction on health rights and existing tribunal mandates.	Amend the Bill to explicitly preserve the jurisdiction of the High Court on health-related rights under the Constitution. Also, clearly define the scope of the new Tribunal to exclude mandates already covered by specialized tribunals or professional bodies.	The Constitution of Kenya (Article 165) grants the High Court unlimited and original jurisdiction over violations of rights. Creating a tribunal that appears to replace or limit this function is unconstitutional and risks service disruptions, especially in ongoing or sensitive litigation involving PLHIV and other vulnerable populations.

Part IX – Financial Provisions	Establishing a new tribunal and supporting infrastructure will create new financial burdens on an already strained health budget.	Direct funding to strengthen existing entities like KHPOA, KHRRAC, HIV/AIDS Tribunal, and SHIF Tribunal. The Healthcare Tribunal should be clean, using existing infrastructure where possible.	Creating new structures duplicates roles, burdens taxpayers, and diverts funds from service delivery. Leveraging existing institutions improves sustainability, efficiency, and builds on already functional legal administrative ecosystems.
Transitional Provisions	Bill proposes implementation within 6 months, risking disruption of services especially for those who rely on the HIV/AIDS Tribunal.	Provide a minimum 12-month transition period. Conduct stakeholder consultations (including CSOs, PLHIV networks, tribunal staff) and develop a phased handover plan if any changes are to occur.	A 6-month window is too short to ensure continuity of legal services, transition of cases, public awareness, training of tribunal members, and system integration. This risks denial of justice and disruption of protection for people with HIV and others.
General Provisions	The Bill risks reducing legal accessibility for vulnerable groups like PLHIV by removing their dedicated tribunal with community-based knowledge and processes.	Maintain access to dedicated grievance mechanisms for HIV/AIDS related issues. A general tribunal should not replace or absorb mechanisms tailored to sensitive, high stigma cases.	Vulnerable groups require safe, knowledgeable, and specialized spaces to raise issues of rights violations, stigma, and treatment access. Centralizing jurisdiction risks intimidating or deterring access to justice, especially for marginalized or criminalized populations.
Schedule 1 and 2	Details missing or unclear. It is uncertain how transition of cases, composition, and existing tribunal mandates are handled in the Schedules.	Amend Schedules 1 and 2 to explicitly protect existing tribunal mandates, define the scope of the new Healthcare Tribunal, and outline how active cases will be managed during transition.	Lack of clarity on transition and jurisdiction in the Schedules may lead to legal ambiguities, misinterpretation, and interruptions in ongoing tribunal processes. Clear drafting will ensure continuity of justice and protect community trust in health-related grievance mechanisms.

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