PARLIAMENT OF KENYA
THE SENATE
SENATE BILLS DIGEST

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

Sponsor: The Leader of the Majority Party, National Assembly, and Leader of Majority Party, Senate.
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Committee referred to: Standing Committee on Health
Type of Bill: Ordinary Bill

1. PURPOSE OF THE BILL

The principal object of the Quality Healthcare and Patient Safety Bill (National Assembly Bill No. 41 of 2025) is to give effect to Article 43(1)(a) of the Constitution by establishing a comprehensive legal and institutional framework for the promotion, regulation and continuous improvement of the quality of healthcare in Kenya. The Bill sets out patient rights and corresponding facility obligations, establishes the Quality Healthcare and Patient Safety Authority to register, license, accredit and inspect health facilities, creates a specialised Health Care Tribunal to resolve health-sector disputes, and prescribes offences and penalties for non-compliance with the provisions of the Act.

2. BACKGROUND OF THE BILL

What problem does the Bill seek to address?

Kenya's health sector has for a long time grappled with cases of medical negligence, inconsistent standards of care, fragmented regulation split across the Health Act and numerous professional-regulation statutes, and a growing number of unlicensed or unregulated facilities operating with limited oversight. There is currently no single statute that consolidates standard-setting, licensing, accreditation, inspection and enforcement in relation to the quality and safety of healthcare services, nor is there a dedicated framework guaranteeing patients an enforceable set of rights and a clear avenue for redress. This has left patients vulnerable to substandard care and has undermined public trust in both public and private health facilities.

What does the law currently provide?

The right to the highest attainable standard of health, including reproductive health care, is guaranteed under Article 43(1)(a) of the Constitution of Kenya, 2010. At the

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

Why the Bill?

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

3. OVERVIEW OF THE BILL

What does the Bill regulate?

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

Responsibilities of the Cabinet Secretary

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

Responsibilities of County Governments

Clause 6 requires each county government to –

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

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

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

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

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

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

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

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

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

Patient Rights and Corresponding Duties

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

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

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

The Quality Healthcare and Patient Safety Authority

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

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

Registration, Licensing and Accreditation of Health Facilities

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

Inspections, Investigations and Enforcement

Clauses 72 to 82 provide for the appointment of health facility inspectors by the Authority by notice in the Gazette. The inspectors are empowered to enter, search,

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

The Health Care Tribunal

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

Financial Provisions and Regulations

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

Offences and Penalties

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

Obstructing an inspector, supplying false information in an accreditation application, or failing to comply with a request for records each attract fines of up to two million

shillings or imprisonment of up to two years, or both. A general penalty of a fine not exceeding ten million shillings or imprisonment for a term not exceeding ten years, or both, applies to any offence for which no other penalty is prescribed.

Transitional Provisions and Consequential Amendments

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

4. CONSEQUENCES OF THE BILL

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

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

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

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

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

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

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

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

5. WAY FORWARD

What next?

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

What is expected of members of the public?

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

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