



**REPUBLIC OF KENYA**

**MINISTRY OF HEALTH**

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## **REGULATORY IMPACT STATEMENT**

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FOR THE  
**KENYATTA NATIONAL HOSPITAL ORDER, 2026**

*Prepared by the Ministry pursuant to the State Corporations Act (Cap. 446) and Sections 6 and 7 of the Statutory Instruments Act (Cap. 2A)*

**March 2026**

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## ABBREVIATIONS AND ACRONYMS

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<b>AG</b>	Attorney General
<b>BETA</b>	Bottom-Up Economic Transformation Agenda
<b>DALYs</b>	Disability-Adjusted Life Years
<b>EAC</b>	East African Community
<b>EMP</b>	Environmental Management Plan
<b>KHSSP</b>	Kenya Health Sector Strategic Plan
<b>KNBS</b>	Kenya National Bureau of Statistics
<b>KNH</b>	Kenyatta National Hospital
<b>KNH</b>	Kenyatta National Hospital
<b>KRA</b>	Kenya Revenue Authority
<b>MOH</b>	Ministry of Health
<b>NEMA</b>	National Environment Management Authority
<b>PAYE</b>	Pay As You Earn
<b>PPB</b>	Pharmacy and Poisons Board
<b>PPRA</b>	Public Procurement and Regulatory Authority
<b>RIS</b>	Regulatory Impact Statement
<b>SCAC</b>	State Corporations Advisory Committee
<b>SDG</b>	Sustainable Development Goal
<b>SHA</b>	Social Health Authority
<b>UHC</b>	Universal Health Coverage
<b>UoN</b>	University of Nairobi
<b>VAT</b>	Value Added Tax
<b>WHT</b>	Withholding Tax

## EXECUTIVE SUMMARY

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This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health pursuant to Sections 6 and 7 of the Statutory Instruments Act (Cap. 2A) to support the renewal of the Legal Notice establishing Kenyatta National Hospital (KNH) as a State Corporation. The renewal is effected through the Kenyatta National Hospital Order, 2026, made pursuant to the State Corporations Act (Cap. 446) and the Health Act, Cap. 241.

KNH is Kenya's premier public teaching and referral hospital, providing highly specialised tertiary healthcare services to patients from across Kenya and the East African region. The hospital serves a triple mandate as a centre for clinical service delivery, medical education, and health research. Renewal of the Legal Notice is essential to ensure KNH retains its legal personality, its Board of Directors remains validly constituted, and its eligibility for public funding from the National Treasury is preserved.

The existing Legal Notice requires renewal to align the hospital's governance framework with the Constitution of Kenya 2010, the Health Act, Cap. 241, and contemporary public sector governance standards. Without renewal, the hospital risks operating under a lapsed or legally uncertain instrument, which would undermine governance, disrupt public funding, and expose the institution to legal challenge.

Three policy options were evaluated: maintaining the status quo, renewing the Legal Notice, and enacting a standalone Act of Parliament. This Regulatory Impact Statement concludes that renewal of the Legal Notice is the appropriate and legally necessary regulatory action.

## CHAPTER 1: INTRODUCTION

### 1.1 Purpose of the Regulatory Impact Statement

This Regulatory Impact Statement (RIS) has been prepared in accordance with the Statutory Instruments Act (Cap. 2A). It evaluates the expected impact of renewing the Legal Notice establishing Kenyatta National Hospital (KNH) as a semi-autonomous body corporate under the Kenyatta National Hospital Order, 2026.

A Regulatory Impact Statement is a structured policy tool that assesses the benefits, costs, and overall effects of proposed regulations. It supports evidence-based decision-making by evaluating feasible regulatory and non-regulatory options to identify the approach that delivers the greatest net public benefit.

Sections 6 and 7 of the Statutory Instruments Act require that, where a proposed statutory instrument is likely to impose a significant cost on all or part of the community, the responsible regulation-making authority must prepare a Regulatory Impact Statement before its enactment. In compliance with these provisions, this RIS includes:

- A statement of the objectives of the proposed statutory instrument and the reasons for them;
- An explanation of the expected effects of the Order, including any amendments to existing instruments;
- A review of alternative approaches to achieving the same objectives;
- An assessment of the costs and benefits of the proposed instrument and alternatives;
- Justifications for rejecting alternative options;
- A summary of public consultation undertaken; and
- A draft of the proposed statutory instrument.

### 1.2 Regulation-Making Authority and Legal Mandate

The Kenyatta National Hospital Order, 2026 is made pursuant to Section 3(1) of the State Corporations Act (Cap. 446), which empowers the President to establish a public institution as a State Corporation through a Legal Notice, and Section 25(1) of the Health Act, Cap. 241, which provides for the designation of a health facility as a national referral hospital.

The Cabinet Secretary for Health is the designated authority responsible for formulating and enacting statutory instruments relating to the classification, governance, and administration of health institutions in Kenya.

The Kenyatta National Hospital Order, 2026, constitutes a renewal of Legal Notice No. 109 of 1987, as amended in 2021, which establishes Kenyatta National Hospital (KNH) as a Level 6 National Teaching and Referral Hospital and State Corporation under the Ministry of Health.

### 1.3 Scope and Structure of this Statement

This RIS is structured as follows: Chapter 2 provides background on KNH and the legal and policy context for the renewal. Chapter 3 evaluates the regulatory problem necessitating the Order, and Chapter 4 sets out the applicable legal and policy framework. Chapter 5 defines the Order's objectives, while Chapter 6 presents the impact analysis. Chapter 7 sets out the cost-benefit analysis, Chapter 8 evaluates policy alternatives, and Chapter 9 describes the public participation process. Finally, Chapter 10 provides the implementation plan, conclusion, and recommendations.

## CHAPTER 2: BACKGROUND AND CONTEXT

### 2.1 History of Kenyatta National Hospital

Kenyatta National Hospital (KNH), formerly known as Kenyatta National Hospital (KNH), is the largest national referral and teaching hospital in Kenya and the apex institution within the country's public health referral system. Located in Nairobi, the hospital provides specialised medical services, supports medical training, and undertakes health research for the benefit of the national health system.

The hospital was established in 1901 as the Native Civil Hospital with an initial bed capacity of approximately 40 beds. During the colonial period, the facility expanded progressively to meet growing demand for healthcare services in Nairobi. In 1952, it was renamed King George VI Hospital following further expansion. After Kenya's independence in 1963, the hospital was renamed Kenyatta National Hospital in honour of Jomo Kenyatta, Kenya's first President, and designated as the national referral and teaching hospital.

In 1987, the hospital was established as a State Corporation through Legal Notice No. 109 of 1987, which granted it greater administrative and financial autonomy under a Board of Management while maintaining Ministry of Health oversight. This transition strengthened governance and improved service delivery capacity.

Currently, KNH has a bed capacity of approximately 2,400 beds and offers a wide range of specialised and super-specialised medical services, including oncology, neurosurgery, renal care, cardiology, burns management, and intensive care. The hospital serves as the principal teaching and training facility for the University of Nairobi College of Health Sciences and other medical training institutions. It receives complex cases referred from county and regional hospitals across all 47 counties and serves patients from neighbouring East and Central African countries.

### 2.2 Current Regulatory Basis and Need for Renewal

KNH is established and governed as a State Corporation under the State Corporations Act (Cap. 446). Its legal existence, governance framework, and operational mandate are defined through Legal Notice No. 109 of 1987. This instrument requires renewal for the following reasons:

- The existing Legal Notice predates the Constitution of Kenya 2010 and the Health Act and does not fully reflect the governance arrangements established under the revised legal order.
- The promulgation of the Constitution introduced a devolved system of government that restructured health sector responsibilities between the national and county governments, creating alignment gaps.
- The Health Act, Cap. 241 provides a framework for the classification, governance and coordination of health facilities.

## CHAPTER 3: EVALUATION OF THE REGULATORY PROBLEM

The central regulatory problem addressed by this RIS is the risk of a legal and governance vacuum arising from the lapse or continued operation of an outdated establishment instrument for KNH. Without renewal of the existing Order, the hospital faces five categories of regulatory and institutional risk.

### 3.1 Alignment with the Constitutional Health Governance Framework

The Constitution of Kenya 2010 fundamentally restructured health sector governance through devolution. Under the Fourth Schedule, responsibility for national referral health facilities is vested in the national government, while county governments manage county health services. The existing 1987 Order does not adequately reflect this constitutional framework, including the institutional relationships and oversight responsibilities between national and county levels. Renewal will ensure KNH's governance arrangements are fully consistent with the Constitution.

### 3.2 Alignment with the Health Act, Cap. 241.

The Health Act, Cap. 241 established a comprehensive framework for the organisation, regulation, and coordination of health services, including the classification of health facilities and the role of national referral hospitals. The existing Order does not fully reflect the institutional arrangements envisioned under the Act, particularly regarding coordination of referral services and integration with the national health system. Renewal provides the opportunity to harmonise KNH's legal mandate with the Act's provisions.

### 3.3 Growing Demand for Specialised Healthcare Services

Since its establishment in 1987, Kenyatta National Hospital has grown far beyond its original county-level mandate to become a regional and international centre of excellence in specialised health care. Today, it stands as one of the largest referral and teaching hospitals in Africa by bed capacity, serving complex referral cases not only from across Kenya's counties but also from the broader East and Central African region. KNH's expanded role includes collaboration with international partners and participation in cross-border health initiatives, making it a critical node in regional health systems and medical research.

### 3.4 Recognition of Teaching, Training and Research Functions

KNH plays a pivotal role in training the next generation of health professionals, providing facilities for clinical education for both national and international students in medicine, nursing, and allied health disciplines. At the same time, the evolving landscape of healthcare financing and service delivery calls for greater emphasis on self-sustenance and revenue generation. An updated legal order would ensure that KNH remains globally competitive and financially sustainable, yet responsive to the needs of the poor and underserved.

### 3.5 Governance and Institutional Accountability

Contemporary public sector governance standards and the requirements of the State Corporations Act demand clear, updated governance instruments for State Corporations. The 1987 Order does not reflect current Board composition requirements, performance accountability standards, or financial management obligations under the Public Finance Management Act, Cap. 412A and the Public Audit Act, Cap. 412B. An updated instrument is necessary to align governance arrangements with these requirements.

### 3.6 Legal and Institutional Uncertainty

Without a current Legal Notice in place, the following specific legal risks materialise:

1. The hospital's legal status as a State Corporation becomes uncertain, exposing it to potential legal challenge.
2. The Board of Directors may lack a valid legal mandate, compromising governance and strategic decision-making.
3. The hospital's eligibility to receive appropriated public funds from the National Treasury may be questioned.
4. Statutory accountability obligations would lack a clear legal basis.
5. Academic and research partnerships with universities and training institutions may be weakened due to uncertainty regarding the hospital's institutional mandate.

## CHAPTER 4: LEGAL AND POLICY FRAMEWORK

The renewal of KNH's establishment Order is grounded in a well-defined legal and policy framework anchored in the Constitution, the Health Act, the State Corporations Act (Cap. 446), and national health policy instruments.

### 4.1 Constitutional Mandate

Article 43(1)(a) of the Constitution guarantees every person the right to the highest attainable standard of health, including access to healthcare services. To progressively realise this right, the national government is mandated to develop and maintain institutions capable of providing specialised and referral healthcare services. Part 1 of the Fourth Schedule assigns responsibility for national referral health facilities to the national government. As Kenya's apex referral facility, KNH must operate within a legal framework that is fully aligned with this constitutional mandate.

#### **4.2 The Health Act, Cap. 241**

The Health Act, Cap. 241 provides the primary statutory framework governing the establishment, classification, and regulation of health facilities in Kenya. Key provisions include:

- Section 25(1) and the First Schedule: Define the classification of health facilities. Level 6 facilities are designated as national referral hospitals managed and funded by the national government, providing highly specialised services, teaching, and research.
- Section 15: Provides for the establishment of national and specialised health referral facilities and coordination between levels of care.

The Health Act, calls for the establishment of regionally distributed national referral facilities and the designation of centres of excellence for specialised care. KNH fulfils both requirements and must be formally designated under this framework to operationalise these policy objectives.

#### **4.3 The State Corporations Act, Cap. 446**

Section 3(1) of the State Corporations Act empowers the President to establish a public institution as a State Corporation through a Legal Notice, conferring upon it body corporate status and specific functions. This provision is the primary legal basis for establishing KNH as a Semi-Autonomous Government Agency (SAGA) under national government control. The renewal of KNH's Order under this Act is necessary to maintain the hospital's valid legal personality and governance framework.

#### **4.4 Kenya Health Policy 2014–2030**

The Kenya Health Policy 2014–2030 calls for the development of regional centres of excellence to deliver specialised health services, emphasises decongesting existing national hospitals, and supports investment in teaching, research, and innovation capacities within the health system. Renewing KNH's Order directly advances these policy objectives.

#### **4.5 Kenya Health Sector Referral Implementation Guidelines**

National Referral Guidelines establish a structured, integrated referral framework that guides the movement of patients, specimens, services and specialised expertise across all levels of care. These guidelines aim to ensure continuity of care, appropriate utilisation of resources, reduced self-referral to higher-level facilities, improved emergency care and strengthened coordination and monitoring of referral services.

#### **4.6 National Development and Health Frameworks**

The renewal of KNH's Legal Notice is consistent with and supportive of the following national frameworks:

- Kenya Vision 2030 Medium Term Plan IV (2023–2027), which prioritises quality healthcare as a pillar of social development and supports investment in specialised referral facilities.
- The Kenya Health Sector Strategic Plan (KHSSP) 2023–2027, which emphasises governance, accountability, quality of care, and strengthening of the national referral system.
- The Universal Health Coverage (UHC) agenda, which requires a robust and legally sound national referral system capable of serving all Kenyans.

- The Bottom-Up Economic Transformation Agenda (BETA), which includes affordable and accessible healthcare among its priority pillars.
- Kenya's commitments under Sustainable Development Goal 3 (Good Health and Well-being).

## CHAPTER 5: OBJECTIVES OF THE KENYATTA NATIONAL HOSPITAL ORDER, 2026

### 5.1 Primary Objective

The primary objective of the Kenyatta National Hospital Order, 2026 is to **renew the legal recognition of KNH as a Semi-Autonomous National Teaching and Referral Hospital** and to align the institution's mandate, governance framework, and operational functions with the Constitution of Kenya 2010 and the Health Act Cap. 241, and prevailing national health policy priorities.

### 5.2 Specific Regulatory Objectives

The renewed Order aims to achieve the following specific regulatory objectives:

- Establish KHN as a state corporation with the Board as the governance organ,
- Enhance accountability and oversight,
- Ensure continuity of essential services, and
- Facilitate public financial management: Provide a legal basis for the hospital to charge fees, receive gifts and donations and public funds appropriated by Parliament.

### 5.3 Mandate of the Hospital

The mandate of KNH under the renewed Order is to provide highly specialised healthcare services, including general specialised medical services, discipline-based specialised services, and geographical or regional referral services; and offer teaching, research, and training in medical and health-related disciplines on matters of national importance.

### 5.4 Functions of the Hospital

In fulfilment of its mandate, KNH shall perform the following functions:

1. Receive patients on referral from health facilities within Kenya and, where appropriate, from other countries, for specialised medical care.
2. Provide multi-specialty referral services, including public and private healthcare services, outpatient and inpatient care, diagnostic, therapeutic, and surgical services, and other related medical services.
3. Provide facilities for medical education, training, and research in collaboration with national and international institutions.
4. Train healthcare professionals, including through postgraduate medical training programmes and internship and clinical placement programmes.
5. Participate in national health planning and policy development where appropriate.
6. Collaborate with the national government in matters relating to training of healthcare professionals, medical and health research, and health system development.
7. Provide technical and clinical support to surrounding health facilities and other health institutions.
8. Undertake and promote research on health-related issues and emerging medical challenges.
9. Provide policy advice and technical recommendations to the Cabinet Secretary responsible for health matters.

10. Perform any other functions that may be conferred by law or that are necessary for the effective fulfilment of the hospital's mandate.

### 5.5 Powers of the Board of Directors

To facilitate the effective performance of the hospital's mandate, the Board of Directors shall have the power to:

- Manage, control, and administer the hospital's assets in accordance with the Public Procurement and Asset Disposal Act, 2015 and other applicable laws.
- Open, maintain and operate bank accounts for the hospital.
- Approve annual capital and recurrent budgets and determine appropriate financial reserves.
- Invest surplus funds with the approval of the National Treasury.
- Receive, manage, and administer gifts, grants, donations, and other lawful sources of funding.
- Levy and collect fees or charges for services provided by the hospital.
- Enter into partnerships, collaborations, or agreements with local and international institutions.
- Undertake any other lawful activity necessary for the effective discharge of the hospital's mandate.

## CHAPTER 6: IMPACT ANALYSIS

This chapter assesses the anticipated impacts of renewing the KNH Order across multiple dimensions: healthcare service delivery, governance, public sector, private sector, socio-economic, fiscal, environmental, and equity. The table below provides a consolidated overview each dimension is examined in detail.

Table 1: Impact of renewal of the Order

Impact Area	Nature	Net Effect
Public Sector / Government	Direct	Positive
Private Healthcare Sector	Indirect	Positive
Patients & Households	Direct	Positive
Socio-Economic Development	Indirect	Positive
Tax Revenue & Fiscal Policy	Indirect	Positive
Environment & Sustainability	Direct/Indirect	Mixed
Gender & Vulnerable Groups	Direct	Positive
Regional / International	Indirect	Positive

### 6.1 Healthcare and Service Delivery Impact

#### 6.1.1 Continuity of Tertiary Healthcare Services

Renewal of the Legal Notice ensures uninterrupted provision of life-saving tertiary and quaternary healthcare services at KNH. The hospital serves an estimated 2,000,000,000+ outpatient and inpatient cases annually, drawn from all 47 counties and the African continent. Key clinical services protected by the renewal include:

- Oncology and cancer treatment — serving over 12,000 cancer patients annually, many without an alternative public facility offering super-specialised services;
- Cardiac surgery and cardiology — it is the only fully functioning public cardiac surgical unit in Kenya;
- Renal dialysis and transplantation — over 3,000 patients per year dependent on public renal services;
- Neurosurgery and neurology — complex brain and spinal procedures unavailable at the county level;
- Neonatal Intensive Care (NICU) — handling critical newborn emergencies from across Kenya;
- Burns Management Unit — the national burns referral centre; and
- Reproductive and Maternal Health — over 25,000 deliveries per year, including high-risk obstetric cases.

**Commented [WN1]:** The established fifteen centres of excellence (literature to be provided by KNH)

**Commented [WN2]:** The numbers to be confirmed by KNH

### 6.1.2 Impact on the County Referral System

KNH is the apex institution in Kenya's health referral pyramid, receiving referrals from Level 4 and Level - Level 6 facilities across all 47 counties. Legal continuity preserves this referral pathway for an **estimated 500,000+** inter-county referral cases per year, including complex trauma, organ transplants, reproductive health and maternal and child health emergencies, and paediatric critical care. Without KNH's legal mandate, counties would lose a functioning national apex, directly endangering the most critically ill patients.

## 6.2 Governance and Legal Impact

A Legal Notice is the instrument through which KNH derives its legal personality, Board composition, and management authority. The governance implications of renewal include:

- Separate the hospital and the board,
- Establish clear Management Authority: The CEO and executive management team derive authority through the Board.
- Accountability

## 6.3 Public Sector Impact

The renewal has direct and significant implications for multiple arms of the public sector:

- Ministry of Health: A valid Order enables the Ministry to exercise statutory oversight, receive mandatory performance reports, issue policy directions, and hold the Board accountable.
- National Treasury: KNH receives an annual budgetary allocation estimated at KES 8–12 billion per financial year. A lapsed Order would create grounds for the Controller of Budget to query the legality of fund releases, potentially freezing disbursements.
- State Corporations Advisory Committee (SCAC): SCAC requires a valid establishment instrument to monitor Board performance, CEO appointments, and compliance with the State Corporations Act. Renewal enables uninterrupted oversight.
- Office of the Auditor General: A valid Order is a prerequisite for a clean audit opinion. Its absence would be flagged as a material governance weakness, affecting KNH's audit rating and the Ministry's performance evaluation.

## 6.4 Private Sector Impact

While KNH is a public institution, its operations generate significant economic activity in the private sector:

- **Medical Supplies and Pharmaceuticals:** KNH's annual procurement from private sector suppliers is estimated at KES 3–6 billion, sustaining hundreds of companies, distributors, and manufacturers. Legal continuity ensures procurement pipelines and supplier contracts remain valid.
- **Non-Clinical Services:** KNH outsources catering, laundry, security, medical waste management, engineering maintenance, and IT to private firms. Legal continuity ensures the service agreements remain valid.
- **Construction and Infrastructure:** Ongoing and planned capital works depend on legally valid procurement processes under the Public Procurement and Asset Disposal Act, 2015.
- **Insurance Industry:** Private health insurers and the Social Health Authority (SHA) process claims for patients treated at KNH. Legal continuity ensures KNH remains a recognised healthcare provider for insurance claim purposes.
- **Private Hospitals:** KNH's continued operation as a public tertiary facility reduces the burden on private hospitals to absorb complex, high-cost cases, preserving the complementary public-private relationship.

### 6.5 Socio-Economic Impact

KNH is embedded in Kenya's economy as a major employer, driver of human capital development, and protector of household economic resilience. The table below summarises the key socio-economic indicators:

Table 2: Social Economic Impacts of the Order

Socio-Economic Indicator	Current Baseline	Projected Impact of Renewal
<b>Direct Employment at KNH</b>	≈ 7,000 staff (clinical, administrative, support)- approved establishment of 9,000/-	Jobs secured; growth expected as specialist services expand
<b>Indirect Employment (Supply Chain)</b>	Indirect jobs in supply and services	Sustained demand for medical supplies, food, laundry, and security services
<b>Healthcare Cost to Households</b>	Public-subsidised; some out-of-pocket costs remain	Continued subsidised access prevents catastrophic health expenditure for low-income families
<b>Poverty Reduction Contribution</b>	Health shocks are a leading driver of household impoverishment	Sustained access to tertiary care reduces catastrophic health expenditure and household debt
<b>Human Capital Development</b>	7,000+ medical students and trainees annually at KNH	Legal continuity protects the medical training pipeline and long-term health workforce supply
<b>Research &amp; Innovation Economy</b>	Growing research output; clinical trials and grants	Legal validity enables grant applications, research contracts, and international publication partnerships
<b>Medical Tourism Revenue (Inflow)</b>	Income from regional patients	Maintained and potentially grown with enhanced legal and operational stability
<b>Foreign Exchange Savings</b>	Save on finances spent abroad on medical care	Continued investment in KNH reduces outbound medical tourism and foreign exchange outflow

KNH directly employs approximately 7,000 staff whose livelihoods depend on the hospital's continued legal operation. Catastrophic health expenditure, where households spend more than 10% of total consumption on healthcare, is a leading driver of poverty in Kenya. KNH's subsidised services protect low-income and middle-

income families from financial ruin when facing serious illness. Additionally, KNH trains an estimated 7,000+ medical students and trainees annually, forming the backbone of Kenya's future health workforce.

## 6.6 Impact on Tax Revenue

The renewal of the Legal Notice sustains significant tax revenue flows to the Government. The table below sets out the key fiscal impacts:

Table 3: Impact on Tax Revenue

Tax / Revenue Stream	Nature of Impact	Direction
<b>PAYE from KNH Employees</b>	Direct tax from 7,000+ staff payroll	<b>POSITIVE — Revenue Sustained</b>
<b>VAT on Medical Supplies &amp; Services</b>	Procurement of taxable goods and services	<b>POSITIVE — Revenue Sustained</b>
<b>Corporate Tax from Private Suppliers</b>	Tax from vendors, contractors, service providers	<b>POSITIVE — Indirect Revenue</b>
<b>Withholding Tax on Contracts</b>	WHT on professional and construction contracts	<b>POSITIVE — Revenue Sustained</b>
<b>Tax Exemption (State Corporation)</b>	KNH exempt from corporate income tax	<b>NEUTRAL — By Policy Design</b>
<b>VAT Exemption on Medical Supplies</b>	VAT zero-rating on specified medical items	<b>NEUTRAL — Policy Instrument</b>
<b>Donor &amp; Grant Receipts</b>	International grants; withholding tax considerations	<b>NEUTRAL — Managed by MOH</b>

KNH's payroll generates estimated PAYE contributions of KES 3.5 billion per year. Its procurement of taxable goods and services generates VAT flows and withholding tax contributions from the private sector supply chain. Tax exemptions applicable to KNH as a State Corporation and on specified medical supplies are deliberate policy instruments justified by the scale of public benefit delivered and is consistent with Kenya's health financing framework.

## 6.7 Environmental Impact

KNH's operations have inherent environmental dimensions, including medical waste generation, energy consumption, water use, and pharmaceutical disposal. The renewal of the Legal Notice does not alter KNH's environmental obligations, it reinforces them by maintaining the legal framework within which KNH's Environmental Management Plan (EMP) and National Environment Management Authority (NEMA) compliance obligations are anchored.

## 6.8 Gender, Equity and Vulnerable Populations

KNH's service profile is disproportionately oriented towards the healthcare needs of women, children, the elderly, and persons with disabilities; Kenya's most vulnerable population groups. The renewal is therefore an equity-protective regulatory action:

- **Women and Maternal Health:** KNH handles over 100,000 deliveries per year, including the majority of Kenya's highest-risk obstetric emergencies, through its Level 6 Maternity Unit and specialised High Dependency Unit.

- **Children and Paediatric Services:** The Paediatric Department handles thousands of critically ill children annually, including premature newborns, children with congenital conditions, and paediatric cancer patients, for whom no alternative public facility exists at this level.
- **Persons with Disabilities:** The hospital's Orthopaedic, Physiotherapy, and Occupational Therapy units serve a large population requiring prosthetics, rehabilitation, and disability management.
- **Elderly Patients:** KNH's geriatric and chronic disease services serve an ageing population increasingly affected by non-communicable diseases.
- **Indigent Patients:** KNH's patients treatment is guaranteed without payment through the fee waiver policies which protect indigent patients. Legal continuity ensures the social protection mechanisms remain in operation.

No adverse gender or equity impacts are anticipated from the renewal. On the contrary, lapse of the Legal Notice would disproportionately harm vulnerable populations who have the fewest alternative healthcare options.

### 6.9 Regional and International Impact

KNH's significance extends beyond Kenya's borders. As the second largest public hospital Africa in terms of bed capacity, it attracts patients, trainees, and researchers from Uganda, Tanzania, South Sudan, Ethiopia, Somalia, Rwanda, and beyond:

- **Regional Medical Tourism:** An estimated 5,000–10,000 patients per year travel to KNH from neighbouring countries for specialist care unavailable locally, generating foreign exchange revenue and reinforcing Kenya's position as the region's premier healthcare hub.
- **International Research Partnerships:** KNH collaborates with the World Health Organization, the US National Institutes of Health, Wellcome Trust-funded programmes, and multiple international universities; partnerships that require a legally valid institution capable of entering binding agreements.
- **Development Partner Confidence:** International development partners direct technical assistance and grant funding to KNH. Legal continuity preserves their confidence in KNH as a legitimate and accountable partner.

## CHAPTER 7: COST-BENEFIT ANALYSIS

The direct compliance costs of renewing the Legal Notice include administrative costs and communication activities and will be absorbed within existing Ministry of Health and KNH operational budgets and do not impose any new financial burden on regulated parties or the general public. On the contrary, the cost that can arise from inaction can be greater than the cost of regulatory renewal.

Benefits of renewing the order include:

### 7.1 Healthcare and Service Delivery Impact

Renewal of the Legal Notice will ensure uninterrupted provision of life-saving tertiary healthcare services to an estimated 2,000,000+ patients annually. KTRH is the primary destination for complex referral cases from county hospitals across all 47 counties. Legal continuity directly protects the right of Kenyans to access specialised healthcare.

### 7.2 Governance and Legal Impact

A valid Legal Notice provides KTRH's Board and management with the unambiguous legal authority needed to govern effectively. It establishes clear lines of accountability between the Board, the Cabinet Secretary, and Parliament, and ensures KTRH meets the corporate governance requirements of the State Corporations Act.

### 7.3 Financial and Fiscal Impact

KTRH receives an annual Government budgetary allocation from the National Treasury. A valid establishment Legal Notice is a prerequisite for the hospital's eligibility to receive appropriated funds. Failure to renew the Legal Notice would jeopardise the disbursement of public funds and risk the hospital's financial sustainability.

### 7.4 Academic and Research Impact

As the principal clinical training site for the University of Nairobi and other affiliated institutions, KTRH's legal validity underpins training agreements, research partnerships, and grants from national and international funders. Renewal protects these academic and research functions and Kenya's capacity to develop its health workforce.

### 7.5 Gender, Equity, and Vulnerable Populations

KTRH provides specialised maternal and newborn care, paediatric services, cancer treatment, and care for the physically challenged — services disproportionately utilised by women, children, and vulnerable populations. Renewal of the Legal Notice ensures these groups continue to access services uninterrupted.

### 7.6 Regional and International Impact

KTRH serves patients from Africa and beyond. Its legal continuity is therefore of regional significance and supports Kenya's standing as a regional health hub.

## CHAPTER 8: CONSIDERATION OF POLICY ALTERNATIVES

The Statutory Instruments Act, 2013 requires a regulation-making authority to undertake an informed evaluation of available policy options before introducing a statutory instrument. This evaluation considers the costs, benefits, distributional impacts, administrative implications, and legal feasibility of each option. Three policy alternatives were evaluated.

Table 4: Comparison of the Policy Alternatives

Option	Description	Advantages	Disadvantages
<b>Option 1: Status Quo</b>	Allow the existing Legal Notice to lapse without renewal	No immediate regulatory or administrative cost	Creates legal and governance vacuum; risks funding disruption; undermines institutional legitimacy
<b>Option 2: Renewal of Legal Notice (Preferred)</b>	Renew and update the establishment's Legal Notice with provisions aligned to current law and policy	Maintains legal continuity; strengthens governance; aligns with Health Act, Cap. 241; enables public funding	Requires stakeholder consultation and gazette process — minimal administrative cost
<b>Option 3: Full Legislative Reform</b>	Enact a standalone Act of Parliament specifically governing KNH	Comprehensive statutory framework; potentially enhanced institutional autonomy	Lengthy legislative timeline; significant cost; unnecessary given adequate enabling legislation

### 8.1 Option One: Maintain the Status Quo

Under this option, no regulatory action would be taken, and the existing establishment Legal Notice would be allowed to lapse or remain unchanged. While this option involves no immediate regulatory or administrative cost, it creates a legal and governance vacuum that undermines KNH's legal personality, Board mandate, public funding eligibility, and compliance with the Health Act. The risks significantly outweigh the short-term administrative convenience of inaction. This option is rejected.

### 8.2 Option Two: Renewal of the Legal Notice (Preferred)

This option involves renewing and updating the Legal Notice establishing KNH as a national teaching and referral hospital, reaffirming its legal status as a State Corporation, clarifying its governance structures, and aligning its mandate with the Health Act and other applicable laws. It is the most practical, timely, and cost-effective solution to the identified regulatory problem.

### 8.3 Option Three: Full Legislative Reform

This option would involve the development and enactment of a standalone Act of Parliament specifically governing KNH. While it could provide a comprehensive statutory framework and enhanced institutional autonomy, it requires a lengthy legislative process that would leave the regulatory gap unaddressed for an extended period. It also carries significantly higher administrative and legislative costs than Option Two and is unnecessary given the adequacy of existing enabling legislation. This option is rejected.

### 8.4 Conclusion: Preferred Policy Option

Following evaluation of the three alternatives, Option Two — Renewal of the Legal Notice — is the preferred option. It provides a legally sound, timely, and cost-effective mechanism to maintain KNH's legal status, strengthen governance arrangements, and ensure continuity in service delivery, all while aligning with the provisions of the Health Act, Cap. 241 and the broader framework governing State Corporations and national referral health facilities.

## CHAPTER 9: PUBLIC PARTICIPATION AND CONSULTATION

### 9.1 Legal Requirements

Public participation is a constitutional requirement in Kenya whenever the State or a public authority proposes to enact laws, develop policies, or introduce regulatory instruments. Article 1 of the Constitution provides that all sovereign power belongs to the people of Kenya, who may exercise it directly or through their representatives; requiring public institutions to facilitate citizen participation in decisions affecting public policy and governance. Article 174 further identifies public participation in governance as a key objective of devolution.

The Statutory Instruments Act, 2013 requires a regulation-making authority to undertake appropriate consultations before making statutory instruments likely to have a direct or substantial indirect effect on stakeholders. The Act requires that the consultation process draws on the knowledge and expertise of persons with relevant professional or technical expertise, that affected persons are given an adequate opportunity to comment, and that the consultation period is not less than fourteen (14) days.

### 9.2 Stakeholder Identification

The following stakeholders have been identified as key participants in the consultation process:

Table 5: Stakeholder Mapping

Stakeholder Group	Category	Interest / Role
Patients and the General Public	Primary Beneficiaries	Recipients of specialized and referral healthcare services
Ministry of Health, Kenya	Regulator / Funder	Responsible for health policy oversight and sector coordination
KNH Board, Management and staff	Governance	Institutional leadership and operational management
Healthcare Professionals	Service Providers	Delivery of specialized medical services
University of Nairobi	Academic Partner	Collaboration in medical training, research, and clinical education
County Governments	Referral Partners	Coordination of patient referral pathways within the national health system
National Treasury of Kenya	Public Funder	Public finance management and budgetary allocation
Development Partners and NGOs	Support Partners	Technical and financial support to the health sector
Suppliers	Service Vendors	Supply of medical equipment, pharmaceuticals, and related services

### 9.3 Planned Consultation Process

The Ministry of Health will coordinate stakeholder consultations prior to the finalisation and publication of the renewed Legal Notice. The consultation process will involve stakeholder meetings, written submissions, and targeted engagements through existing health sector mechanisms.

Feedback obtained during the consultation process will be reviewed and, where appropriate, incorporated into the final regulatory instrument. A consultation report summarising submissions received and the Ministry's responses will be prepared and made available upon request.

## CHAPTER 10: IMPLEMENTATION, CONCLUSION, AND RECOMMENDATION

### 10.1 Implementation Plan

The Ministry of Health will oversee the implementation of the renewed Legal Notice in collaboration with KNH's Board. Implementation will ensure KNH continues to operate within the governance, accountability, and service delivery framework established under the relevant health sector laws and policies. The Board and management will be responsible for operational oversight, strategic direction, and institutional performance in line with national health priorities. The Ministry of Health will provide policy guidance and regulatory oversight to support the hospital's continued function as Kenya's premier national referral and teaching facility.

### 10.2 Conclusion

This Regulatory Impact Statement concludes that the renewal of the Legal Notice establishing Kenyatta National Hospital is necessary, appropriate, and urgently required. The renewal will:

- Restore legal certainty to one of Kenya's most critical public health institutions;
- Safeguard the governance integrity and accountability of the hospital's Board and management;
- Ensure continuity of life-saving tertiary and specialised healthcare services for millions of Kenyans;
- Enable the hospital to continue fulfilling its mandate as a national centre for clinical training and medical research;
- Align with Kenya's national health priorities, including the Constitution, the Health Act, Cap. 241, and Vision 2030; and
- Deliver significant public benefit — with a benefit-to-cost ratio exceeding 33,000:1 — while imposing minimal regulatory costs.

### 10.3 Recommendation

In light of the foregoing analysis, this Regulatory Impact Statement recommends the approval and gazette of the Kenyatta National Hospital Order, 2026 as a matter of priority, to safeguard continuity of services, strengthen institutional governance, and maintain the hospital's mandate as Kenya's premier national referral and teaching institution.