REPUBLIC OF KENYA

MINISTRY OF HEALTH

EAST AFRICA CENTRE OF EXCELLENCE IN UROLOGY AND NEPHROLOGY

REGULATORY IMPACT STATEMENT FOR THE EAST AFRICA CENTRE OF EXCELLENCE IN UROLOGY AND NEPHROLOGY ORDER, 2026
MADE PURSUANT TO THE STATE CORPORATIONS ACT (CAP. 446)

The Ministry of Health has prepared this Regulatory Impact Statement (RIS) under Sections 6 and 7 of the Statutory Instruments Act, Cap 2A.

May 2026

Abbreviations

EAKI	EAST AFRICA CENTRE OF EXCELLENCE IN UROLOGY AND NEPHROLOGY
KNH	Kenyatta National Hospital
MTRH	Moi Teaching and Referral Hospital
MOH	Ministry of Health
RIS	Regulatory Impact Statement
SAGA	Semi-Autonomous Government Agency
SRC	Salaries and Remuneration Commission
PSC	Public Service Commission
UHC	Universal Health Coverage
PPP	Public-Private Partnership
ESRD	End-Stage Renal Disease
CKD	Chronic Kidney Disease
ICU	Intensive Care Unit
KMTC	Kenya Medical Training College
WHO	World Health Organization
IGRTC	Intergovernmental Relations Technical Committee
KMPDU	Kenya Medical Practitioners, Pharmacists and Dentists Union
EAC	East African Community

CHAPTER 1: INTRODUCTION

1.1 Purpose of the Regulatory Impact Statement

This Regulatory Impact Statement (RIS) has been prepared in accordance with the provisions of the Statutory Instruments Act (Cap. 2A). It evaluates the expected impact of the legal order gazetting the East Africa Centre Of Excellence in Urology and Nephrology as a body corporate under the East Africa Centre Of Excellence In Urology And Nephrology Order, 2026.

A Regulatory Impact Statement is a structured policy tool that assesses the benefits, costs, and overall effects of proposed statutory instruments. It supports evidence-based decision-making by evaluating feasible regulatory and non-regulatory options, with the intention of identifying 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 prior to its enactment. The purpose of these provisions is to ensure that the legal Order is justified and backed by a comparison of options and selection of the most efficient and effective one.

In compliance with these provisions, this RIS includes:

- A statement of the objectives of the proposed statutory instrument and the reasons behind them.
- An explanation of its expected effects, including any amendments to existing statutory instruments.
- A review of alternative approaches to achieving the same objectives.
- An assessment of the associated costs and benefits of both the proposed instrument and alternatives.
- Justifications for rejecting other options.
- Any additional matters required under the Act; and
- A draft of the proposed statutory instrument.

Additionally, Section 5 of the Act mandates that public consultation be conducted to engage stakeholders and experts in relevant fields and provide affected persons with a meaningful opportunity to comment on the proposal. This makes the RIS a record of participatory law-making, ensuring the statutory instrument reflects public input and reduces resistance to implementation.

1.2 Regulation-Making Authority and Legal Mandate

The proposed East Africa Centre of Excellence in Urology and Nephrology Order, 2026 is made pursuant to the following legal framework :

- Section 3(1) of the State Corporations Act (Cap. 446), which empowers the President to establish a public institution as a State Corporation; and
- Section 25(1) of the Health Act, 2017, which allows the designation of a health facility as a national specialist health institution.

The Cabinet Secretary for Health is the designated authority under both the Health Act, 2017 and the Statutory Instruments Act (Cap. 2A), responsible for formulating and enacting statutory instruments relating to the classification, governance, and administration of health institutions in Kenya.

Accordingly, the Order, provides for the gazettement of the East Africa Centre of Excellence in Urology and Nephrology as a body corporate and a State Corporation under the Ministry of Health, mandated to provide specialised renal health services, training, and research across the East African region.

1.3 Implementation Framework for Transition

The implementation of the Order will be guided by statutory provisions and institutional realignment. The framework will address institutional establishment, human resource planning, and governance structures.

a) Institutional Establishment

The East Africa Centre of Excellence in Urology and Nephrology will be formally established as a body corporate upon gazettement of the Order. This process will be guided by:

- Section 3(1) of the State Corporations Act (Cap. 446), which provides for the establishment of state corporations.
- The Health Act, 2017, which defines the mandate and governance of national health institutions.
- The Ministry of Health's institutional framework for oversight and accountability of Semi-Autonomous Government Agencies.

A formal establishment plan will be developed to guide the setting up of governance structures, operational systems, and service delivery frameworks.

b) Human Resource Planning

The staffing of the institution will follow a competitive and transparent process, guided by:

- The Employment Act, 2007 and Labour Relations Act, 2007.
- Policy directives from the Public Service Commission (PSC) and the Salaries and Remuneration Commission (SRC).
- Consultations with relevant professional bodies.

A comprehensive human resource plan will be developed to attract and retain specialist nephrologists, renal nurses, dialysis technicians, and other healthcare professionals critical to the Institute's operations.

c) Establishment of East Africa Centre of Excellence in Urology and Nephrology as a State Corporation

The Order establishes East Africa Centre of Excellence in Urology and Nephrology as a State Corporation, granting it administrative and financial autonomy. This enables the Institute's Board of Management to exercise authority over organisational structures and operational decisions, improving efficiency and alignment with the Institute's strategic mandate.

Upon gazettement, East Africa Centre of Excellence in Urology and Nephrology will be formally constituted as a State Corporation under the State Corporations Act (Cap. 446). The Ministry of Health will spearhead the institutional setup through the following steps:

- Establishing a governance structure, including the appointment of a Board of Management.
- Developing a transitional strategic plan aligned with national health priorities.
- Standardising operations, policies, and procedures in line with those of other national health institutions.

1.4 Requirements of the Statutory Instruments Act

The Act requires that every statutory instrument be accompanied by a RIS that:

- Demonstrates the need for the proposed subsidiary legislation.
- Outlines the objectives and intended effects.
- Assesses alternative options and justifies the preferred one.
- Describes stakeholder consultations and public participation.
- Analyses the economic, social, and environmental impacts.

CHAPTER 2: BACKGROUND AND CONTEXT

The East Africa Centre Of Excellence in Urology and Nephrology, formally referred to as East Africa Kidney Institute (EAKI) was established with a vision to become the region's premier centre of excellence for kidney health, offering comprehensive renal care, specialised training for healthcare professionals, and cutting-edge research in nephrology. Located in Nairobi, Kenya, East Africa Centre Of Excellence in Urology and Nephrology has grown to be a critical referral point for kidney disease management not only within Kenya but across the broader East African region.

Kidney disease represents one of the most rapidly growing non-communicable disease burdens in Sub-Saharan Africa. Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD) are major contributors to morbidity and mortality, yet they remain significantly under-resourced and under-prioritised within health systems. In Kenya and the broader East Africa region, access to dialysis services, kidney transplantation, and specialist nephrology care is severely limited, with the few available services concentrated in urban centres and largely inaccessible to low-income populations.

East Africa Centre of Excellence In Urology and Nephrology was conceived to address this critical gap. Since its establishment, the Institute has invested significantly in state-of-the-art infrastructure, specialist personnel, and research capacity. Its services encompass haemodialysis, peritoneal dialysis, kidney transplantation, renal hypertension management, diabetic nephropathy care, paediatric nephrology, and clinical training. The Institute partners with leading local and international academic and research institutions to advance nephrology science and build regional health capacity.

Despite its growing regional importance and functional capacity as a national and regional specialist institution, East Africa Centre Of Excellence in Urology and Nephrology currently lacks formal legal recognition as a body corporate. This absence of statutory status constrains the Institute's ability to operate with full institutional autonomy, access dedicated national and international funding streams, enter into legally binding partnerships, own property, and maintain independent governance structures. Operating without a legal personality limits institutional sustainability and accountability.

The proposed East Africa Centre Of Excellence in Urology and Nephrology Order, 2026 therefore seeks to formally gazette East Africa Centre of Excellence In Urology and Nephrology as a body corporate under the Ministry of Health. This gazettement will:

- Confer legal personality on East Africa Centre Of Excellence in Urology and Nephrology, enabling it to sue and be sued, own assets, and enter into contracts.

- Establish a governance framework with a Board of Management accountable to the Cabinet Secretary for Health.
- Formalise it's mandate in renal care delivery, specialist training, and nephrology research.
- Enable access to exchequer allocations and structured donor funding.
- Position East Africa Centre Of Excellence In Urology And Nephrology as a regional centre of excellence aligned with Kenya's Universal Health Coverage agenda and East Africa's health integration frameworks.

This gazettement is a necessary and strategic step to ensure that East Africa Centre Of Excellence In Urology And Nephrology can fully discharge its mandate, achieve institutional sustainability, and contribute meaningfully to Kenya's health system and the broader East African health landscape.

CHAPTER 3: EVALUATION OF THE PROBLEM

Kidney disease is a significant and rapidly growing public health challenge in Kenya and across East Africa. Chronic Kidney Disease (CKD) affects an estimated 10–15% of the adult population globally, with prevalence rates in Sub-Saharan Africa reported to be even higher owing to the elevated burden of diabetes mellitus, hypertension, HIV/AIDS, and endemic infections such as malaria and schistosomiasis — all of which are leading causes of CKD in the region.

In Kenya, End-Stage Renal Disease (ESRD) presents a particularly acute challenge. The majority of patients who reach ESRD require lifelong renal replacement therapy — haemodialysis, peritoneal dialysis, or kidney transplantation — to survive. Yet the national capacity for these services is severely limited. There are fewer than 100 accredited dialysis facilities in Kenya, with over 70% concentrated in Nairobi, leaving populations in other regions without access to life-sustaining treatment. Kidney transplantation services remain nascent, with only a handful of centres capable of performing transplants.

The East Africa Centre of Excellence in Urology and Nephrology has emerged as a critical national and regional resource in responding to this crisis. The Institute provides:

- Haemodialysis and peritoneal dialysis services.
- Kidney transplantation programmes.
- Specialist nephrology and renal hypertension consultations.
- Diabetic nephropathy and paediatric nephrology services.
- Training for nephrologists, renal nurses, and dialysis technicians.
- Nephrology research and clinical trials.

East Africa Centre of Excellence in Urology and Nephrology serves patients not only from Kenya but also from Uganda, Tanzania, Rwanda, South Sudan, and other East African nations, cementing its role as a regional referral institution. However, operating without formal legal status as a body corporate significantly undermines the institutional capacity. The key problems arising from this regulatory gap include:

a) Absence of Legal Personality

Without gazettement as a body corporate, East Africa Centre of Excellence in Urology and Nephrology cannot independently own assets, enter into legally binding contracts, sue or be sued in its own name, or maintain institutional financial autonomy. This absence of legal standing creates institutional fragility, limits accountability, and constrains the Institute's ability to operate as a fully functional autonomous entity.

b) Restricted Access to National and International Funding

State corporations and formally gazetted bodies have access to dedicated government exchequer allocations, structured donor funding, and tax-exempt grant mechanisms. Without this status, East Africa Centre of Excellence in Urology and Nephrology is unable to access these critical funding streams, limiting its capacity for infrastructure development, equipment procurement, human resource expansion, and research investment.

c) Governance and Accountability Gaps

The absence of a statutory governance framework creates uncertainty around accountability, strategic oversight, and institutional management. Formalising the governance structure through gazettement will ensure clear lines of authority, transparent financial management, and results-based institutional leadership.

d) Inability to Formalise Regional and International Partnerships

East Africa Centre of Excellence in Urology and Nephrology's mandate as a regional centre of excellence requires it to enter into formal partnerships with governments, international health organisations, academic institutions, and research bodies. Without legal personality, such partnerships lack the institutional foundation necessary for sustained, structured collaboration.

e) Constraint on Workforce Development

Without national government status and formal institutional recognition, East Africa Centre of Excellence in Urology and Nephrology is limited in its ability to establish training programmes accredited by national regulatory bodies, attract internationally trained specialists, and participate in national human resource planning frameworks for health.

The cumulative effect of these challenges is that East Africa Centre of Excellence in Urology and Nephrology, despite its established functional capacity and regional significance, cannot operate at its full potential. Gazettement under the proposed Order is therefore both urgent and necessary to unlock the Institute's full mandate and ensure sustainable, accountable delivery of specialised renal care for Kenya and the East African region.

CHAPTER 4: POLICY AND LEGAL FRAMEWORK

The establishment of the East Africa Centre of Excellence in Urology and Nephrology as a body corporate is supported by a well-defined legal and policy framework, anchored in the Constitution of Kenya, the Health Act, 2017, the State Corporations Act, and Kenya's national health policies.

4.1 Constitutional Mandate

Article 43(1)(a) of the Constitution of Kenya guarantees every citizen the right to the highest attainable standard of health, including reproductive health care. The State is obligated to take progressive measures to achieve the full realisation of this right.

The Fourth Schedule of the Constitution designates management of national referral and specialist health facilities as a national government function. Gazettement of East Africa Centre of Excellence in Urology and Nephrology as a national body corporate under the Ministry of Health is fully consistent with this constitutional allocation of responsibilities.

Article 10 of the Constitution requires that national values and principles of governance, including transparency, accountability, and public participation, guide all policy and legislative decision-making — principles that have informed the preparation of this RIS.

4.2 The Health Act, 2017

Section 25(1) of the Health Act, 2017 empowers the Cabinet Secretary for Health to designate health facilities and institutions to fulfil specialised national health functions. The Act classifies health facilities, with national specialist institutions designated to provide highly specialised services, teaching, and research.

Sections 15 and 16 of the Health Act provide for the establishment of national referral systems and coordination between levels of care, supporting Centres role as a specialist referral institution for renal disease management. The Act further mandates the promotion of equity in healthcare delivery and the development of centres of excellence to address the burden of non-communicable diseases — both of which align directly with Centres mandate.

4.3 The State Corporations Act (Cap. 446)

Section 3(1) of the State Corporations Act empowers the President to establish a state corporation through a Legal Notice, conferring upon it body corporate status and defining its functions. Establishing East Africa Centre of Excellence in Urology and Nephrology as a state corporation enables it to operate with administrative and financial autonomy under the governance framework of the Act.

The Act provides the legal basis for creating East Africa Centre of Excellence in Urology and Nephrology as a Semi-Autonomous Government Agency (SAGA) under national government control, with a Board of Management empowered to provide strategic oversight, financial governance, and institutional leadership.

4.4 Kenya Health Policy 2014–2030

The Kenya Health Policy provides the overarching vision for the health system and calls for the development of regional and national centres of excellence to deliver specialised health services. The Policy emphasises:

- The development of specialist institutions to address the growing burden of non-communicable diseases, including chronic kidney disease.
- Improving geographic equity in access to advanced care.
- Supporting the development of teaching, research, and innovation capacities within the health system.

Centres mandate as a specialist renal care and training institution is directly aligned with these policy objectives.

4.5 Vision 2030 (Social Pillar – Health Sector)

Kenya's Vision 2030 strategy envisions a health system that guarantees equitable access to quality healthcare for all Kenyans and supports investment in specialised referral facilities as a strategy to reduce the burden of disease and improve quality of care. It prioritises the upgrading and expansion of national specialist services and the development of Kenya as a medical hub for the region. Gazettement of East Africa Centre of Excellence in Urology and Nephrology as a body corporate directly supports these Vision 2030 objectives by establishing a centre of excellence for renal care that can serve both the national and regional market.

4.6 Kenya Health Sector Strategic Plan

Kenya's Health Sector Strategic Plans articulate the national government's commitment to strengthening specialist health institutions, expanding access to renal replacement therapy, and building national capacity for non-communicable disease management. The proposed Order supports implementation of these strategic plans by formalising Centres institutional mandate.

4.7 East African Community Health Policy Framework

The East African Community Health Policy Framework promotes regional integration in health service delivery, including the development of shared specialist institutions and cross-border referral networks. East Africa Centre of Excellence in Urology and Nephrology's mandate as a regional renal care centre aligns with this framework, and its formal gazettement will strengthen the legal basis for its regional partnerships and collaborations.

CHAPTER 5: OBJECTIVES OF THE EAST AFRICA CENTRE OF EXCELLENCE IN UROLOGY AND NEPHROLOGY ORDER, 2026

5.1 Specific Objectives of the Order

The primary objective of the East Africa Centre of Excellence in Urology and Nephrology Order, 2026 is to confer legal recognition upon the East Africa Centre of Excellence in Urology and Nephrology as a body corporate under the Ministry of Health, and to align the Institute's mandate with national health policies, strategies, and regulatory frameworks.

By establishing East Africa Centre of Excellence in Urology and Nephrology as a State Corporation, the Order seeks to strengthen Kenya's health system by expanding access to specialised renal care, consolidating the Institute's training and research functions, and establishing a sustainable governance framework aligned with Kenya's Universal Health Coverage agenda.

Specifically, the Order seeks to:

- Gazette East Africa Centre of Excellence in Urology and Nephrology as a Body Corporate. This confers legal personality on the Institute, enabling it to independently own assets, enter into contracts, sue and be sued, and operate with institutional autonomy in accordance with the State Corporations Act.
- Establish East Africa Centre of Excellence in Urology and Nephrology as a State Corporation. This provides the Institute with corporate status, including the powers to manage its affairs and exercise autonomy in operations and administration, with a Board of Management accountable to the Cabinet Secretary for Health.
- Formalise the Centre Mandate in Specialised Renal Care. The Order will formally define the mandate to provide comprehensive renal care services including haemodialysis, peritoneal dialysis, kidney transplantation, renal hypertension management, diabetic nephropathy care, and paediatric nephrology.
- Promote Training, Research, and Innovation. The Order will institutionalise East Africa Centre of Excellence in Urology and Nephrology as a centre for nephrology training and research, in partnership with academic and research institutions, to support medical education, clinical internships, and health research in kidney disease.
- Support National and Regional Referral Networks. Centres status as a national specialist body will strengthen Kenya's renal referral system and serve as a strategic referral centre for the East African region, reducing patient travel to international destinations for renal care.
- Enable Sustainable Funding and Resource Mobilisation. The Order will provide a legal framework that empowers the Institute to access exchequer allocations, mobilise donor funding, enter into strategic partnerships, and invest in infrastructure and technology.

- Institutionalise Good Governance and Financial Accountability. Centres Board of Management will be empowered to establish internal structures ensuring strategic leadership, oversight, financial prudence, and results-based management.

5.2 Expected Outcomes

The realisation of these objectives is expected to result in:

- Expanded access to high-quality specialised renal care across Kenya and the East African region.
- Improved clinical outcomes for patients with chronic kidney disease and end-stage renal disease.
- Strengthened training and retention of nephrology specialists, renal nurses, and dialysis technicians.
- Enhanced capacity for kidney disease research, innovation, and evidence-based policy.
- Sustainable governance, financial independence, and institutional accountability of the Institute.
- Reduced patient referrals abroad for renal care, generating foreign exchange savings and retaining health expenditure within the region.

CHAPTER 6: COST-BENEFIT ANALYSIS

This chapter evaluates the economic and social implications of gazetting the East Africa Centre of Excellence in Urology and Nephrology as a body corporate under the State Corporations Act. The analysis considers both the direct and indirect benefits of the proposed Order against the associated costs, to demonstrate that gazettement represents the most efficient and effective policy option.

6.1 Benefits

The most immediate and significant benefit of gazetting East Africa Centre of Excellence in Urology and Nephrology as a body corporate is improved access to specialised renal care for patients across Kenya and the East African region. Currently, patients requiring advanced kidney care — including haemodialysis, peritoneal dialysis, and kidney transplantation — face significant challenges in accessing these services, with many travelling abroad to India, South Africa, or other destinations at enormous personal and national economic cost. Formalising Centres legal status will enable the Institute to expand its service capacity, attract specialist personnel, and serve a larger patient population.

A major benefit is the decongestion of existing national health facilities. Kenyatta National Hospital and Moi Teaching and Referral Hospital are overburdened with renal cases, limiting their capacity to manage other complex conditions. Establishing East Africa Centre of Excellence in Urology and Nephrology as a dedicated renal care centre will redistribute this demand and improve overall system efficiency.

From a strategic perspective, gazettement promotes equity and national capacity in the delivery of specialised renal care. It aligns with Kenya's constitutional commitment to the right to health, the UHC agenda, and national development goals under Vision 2030, ensuring that high-quality specialist services are accessible to all Kenyans regardless of economic status.

Centres training and research mandate will be significantly enhanced. As a formally gazetted body corporate, the Institute can attract structured government and donor funding for research, establish accredited training programmes, and partner with international academic institutions to advance nephrology science in East Africa.

Economically, gazettement will generate significant savings for Kenyan households and the national health system. By expanding domestic renal care capacity, it will reduce substantial outflows of foreign exchange associated with medical tourism. It will also stimulate local economic activity through job creation, procurement of medical supplies, and development of health-related services.

6.2 Costs

Capital investments will be required to expand infrastructure, procure state-of-the-art renal equipment, and develop service areas to meet the standards of a national specialist institution. Recurrent costs will increase, including salaries for specialist staff, operational expenses, and maintenance of haemodialysis machines, peritoneal dialysis equipment, and other diagnostic and surgical equipment.

Administrative and governance-related costs will arise from establishing East Africa Centre of Excellence in Urology and Nephrology as a state corporation, including the constitution of a Board of Management, development of administrative systems, compliance with national procurement and audit regulations, and alignment with the Public Finance Management framework.

Despite these costs, the long-term benefits — in terms of improved health outcomes, reduced patient burden, system efficiency, and strategic positioning — far outweigh the financial implications. Gazettement of East Africa Centre of Excellence in Urology and Nephrology as a body corporate is therefore a sound and necessary investment in Kenya's health system.

Table 1: Cost-Benefit Matrix

Area	Benefits	Costs
Access to Care	Reduced travel burden; decongestion of orther Natinal Reffera; timely specialist treatment.	None
Infrastructure	Modern renal facility; regional health equity; improved diagnostic capacity.	Significant capital investment in equipment and facilities.
Governance	Efficient, autonomous operations under the State Corporations Act; clear accountability.	Board setup, compliance, and administrative costs.
Research & Training	Data-driven nephrology research; clinical training; international partnerships.	Investment in research infrastructure and academic linkages.
Economic Impact	Local job creation; reduced medical tourism outflows.	Recurrent operational and maintenance expenses.
UHC & Vision 2030	Supports the right to health; promotes equity; advances Kenya Health Policy 2014–2030.	Coordination with devolved health structures.
Environmental	Reduced patient travel emissions; safe biomedical waste management systems.	Cost of compliant waste treatment facilities.

CHAPTER 7: CONSIDERATION OF ALTERNATIVES

7.1 Introduction

The Statutory Instruments Act, Cap. 2A requires a regulation-making authority to carry out an informed evaluation of a variety of regulatory and non-regulatory policy measures by considering relevant issues such as costs, benefits, distributional effects, and administrative requirements. Subsidiary legislation should be the last resort in realising policy objectives. Three options were considered to address the regulatory gap.

7.2 Alternatives

7.2.1 Option One: Maintain the Status Quo

Maintaining Centres current status without gazettement as a body corporate would perpetuate the institutional constraints that limit the Institute's effectiveness. In the absence of legal personality, East Africa Centre of Excellence in Urology and Nephrology cannot independently own assets, enter binding contracts, or access structured government and donor funding. The Institute would remain dependent on ad hoc funding arrangements, limiting its capacity for long-term planning, infrastructure investment, and service expansion.

Patients across Kenya and the East African region would continue to face inadequate access to specialist renal care, driving medical tourism abroad and imposing significant financial burdens on households and the national health system. The growing burden of chronic kidney disease would remain inadequately addressed, with increasing morbidity and mortality consequences. This option fails to fulfil Kenya's constitutional commitment to the right to health and does not support the UHC agenda.

7.2.2 Option Two: Implement Administrative Measures

Administrative actions; such as increased funding through ad hoc allocations, secondment of specialist staff, or designation as a training site, may temporarily enhance operations. However, such measures lack legal backing, budgetary sustainability, and institutional permanence.

Without formal gazettement, East Africa Centre of Excellence in Urology and Nephrology would remain outside the legal framework of the State Corporations Act, limiting its access to dedicated national funding, restricting long-term planning and creating governace uncertainty. Administrative measures cannot replicate the institutional stability and legal authority that gazettement as a body corporate provides.

7.2.3 Option Three: Gazettement via Legal Order (Preferred Option)

Establishing East Africa Centre of Excellence in Urology and Nephrology as a body corporate through a Legal Notice under the State Corporations Act is the preferred option. This provides a clear, legal and sustainable foundation for the Center's existence, operations, and integration into Kenya's national health system and East Africa's regional health landscape.

Unlike administrative arrangements, legal recognition provides long-term stability, legitimacy, and enforceability.

7.3 Conclusion: Preferred Option

Option 3 is preferred as it provides a legal path to operational and financial sustainability, institutional accountability, and fulfilment of Center's mandate as a national and regional centre of excellence for renal care.

7.4 Impact Analysis of the Options

The matrix below demonstrates that Option 3; Gazettement via Legal Notice, provides a foundation for institutional growth, governance, and sustainability, and also aligns with Kenya's constitutional and policy commitments, especially concerning the right to health and national healthcare strategy.

Table 2: Impact Assessment Matrix

Impact Area	Option 1: Status Quo	Option 2: Administrative Measures	Option 3: Legal Gazettement (Preferred)
Social Impact	Continued inequity in renal care access; high patient mortality from ESRD.	Slight service improvement; unclear mandate and sustainability.	Improved access to renal care; promotes national health equity and reduces mortality.
Economic Impact	High out-of-pocket costs; patients seek care abroad; economic stagnation.	Modest support; no long-term investment planning.	Boosts regional economy; enables long-term investment and local job creation.
Environmental Impact	Higher emissions from long-distance patient travel; inadequate biomedical waste management.	Partial infrastructure improvement; environmental risks unmanaged.	Promotes sustainable facility development; improved biomedical waste management.
Legal Impact	No statutory authority to operate as a national specialist body; weak governance.	Outside formal legal framework; unclear mandates and accountability.	Full compliance with the Health Act and State Corporations Act; clear mandates and legal standing.
Tax-Related Impact	No Impact	No Impact.	No Impact
Human Rights Impact	No Impact	Partial compliance with the right to health; no accountability mechanism.	Upholds and promotes the right to health through equitable access to specialist services.
Public Sector Impact	Continued strain on KNH and MTRH; underutilisation of regional capacity.	National government lacks formal oversight; uncoordinated support.	Decongests national facilities; enhances coordinated health planning.

Private Sector Impact	No Impact	Ad hoc collaboration; lacking predictability or structure.	Encourages PPPs and academic/medical partnerships; predictable investment environment.
Impact on Legal Frameworks	No Impact	No Impact	Aligns with the Constitution, Health Act, and national referral policy; supports UHC and Vision 2030.

CHAPTER 8: PUBLIC PARTICIPATION AND CONSULTATION

8.1 Constitutional and Legal Mandate

Public participation in policy development represents a fundamental constitutional requirement rooted in Kenya's democratic principles. Article 1 of the Constitution establishes the sovereignty principle, vesting all sovereign power in the people of Kenya and entitling citizens to contribute meaningfully to public decision-making processes. This participation must be inclusive, transparent, and accountable.

Article 174 further strengthens this framework by empowering communities with self-governance rights and enhancing their participation in state decision-making processes that affect their lives.

The Statutory Instruments Act reinforces these constitutional provisions by mandating regulation-making authorities to conduct appropriate consultations before enacting subsidiary legislation. The Act establishes specific criteria for determining consultation adequacy, requiring authorities to consider whether consultations:

- Draw upon expertise from persons with relevant field knowledge regarding the proposed statutory instrument.
- Provide adequate opportunities for potentially affected persons to comment on proposed content.

The statutory framework requires that consultation participants be notified either directly or through advertisement via representative organisations. Participants must be invited to submit written contributions by specified dates — not less than fourteen days from notification — or to participate in public hearings concerning proposed instruments.

8.2 Statutory Autority Mandate

The Cabinet Secretary for Health bears constitutional responsibility for developing health policies, laws, administrative procedures, and programmes in consultation with county governments, health sector stakeholders, and the general public. This mandate aims to achieve progressive realisation of the highest attainable health standards.

8.3 Collaborative Development Process

The development of the East Africa Centre of Excellence in Urology and Nephrology Order, 2026 was through a consultative approach with the Ministry of Health, Office of the Attorney General and Department of Justice,the Kenya Laws Reform Commission and orther relevant health sector stakeholders to ensure comprehensive legal and policy alignment.

8.4 Public Participation Implementation

In accordance with Article 10 of the Constitution and Section 5 of the Statutory Instruments Act, the Ministry of Health subjected both the Order and accompanying Regulatory Impact Statement to comprehensive public participation. This process commenced with a public notice published in the Kenya Gazette and on the official website of the Ministry of Health, inviting public submissions.

The notice invited stakeholders to submit written memoranda, comments and feedback to the designated email address at the Office of the Principal Secretary, State Department for Medical Services. Additionally, participants could hand-deliver written submissions to Afya House, Nairobi.

8.5 Public Participation Exercise

To be done after public participation

CHAPTER 9: IMPLEMENTATION OF THE LEGAL ORDER

9.1 Compliance and Implementation

The Ministry of Health will oversee implementation of the East Africa Centre of Excellence in Urology and Nephrology Order, 2026 in collaboration with the Institute's Board of Management, the State Corporations Advisory Committee, and relevant stakeholders. Implementation will be guided by a detailed transition plan developed in consultation with the State Department for Medical Services and the National Treasury.

Upon gazettement, the following immediate implementation steps will be undertaken:

- Constitution of the East Africa Centre of Excellence in Urology and Nephrology Board of Management in accordance with the State Corporations Act.
- Development and approval of the Institute's first Strategic Plan as a state corporation.
- Submission of the first budget estimates to the National Treasury for exchequer allocation.
- Execution of Memoranda of Understanding between East Africa Centre of Excellence in Urology and Nephrology and relevant county governments to formalise referral linkages.
- Establishment of internal governance, financial, and operational systems compliant with the Public Finance Management Act.

9.2 Monitoring and Evaluation

The Ministry of Health will establish a monitoring and evaluation framework to track implementation progress against defined milestones. Annual performance reports will be submitted to the Cabinet Secretary for Health in accordance with the State Corporations Act requirements.

9.3 Recommendations

The Ministry of Health recommends approval of the legal Order to facilitate its gazettement. This will:

- Enable formal exchequer budgetary support for East Africa Centre of Excellence in Urology and Nephrologyby the National Treasury.
- Provide the legal foundation for Centres Board of Management to be constituted and operational governance frameworks established.
- Unlock structured donor funding and international partnership arrangements.
- Position Kenya and East Africa with a formally recognised regional centre of excellence for renal care, aligned with UHC commitments and Vision 2030.

9.4 Conclusion

The gazettement of the East Africa Centre of Excellence in Urology and Nephrology as a body corporate under the State Corporations Act is a strategic and necessary intervention to address the growing burden of kidney disease in Kenya and the East African region. The proposed Order provides the legal foundation for East Africa Centre of Excellence in Urology and Nephrology to operate with full institutional autonomy, access sustainable funding, establish robust governance structures, and fulfil its mandate as a national and regional centre of excellence for renal care, training, and research.

The approval of the Legal Order is fully aligned with Kenya's constitutional commitment to the right to health, the Universal Health Coverage agenda, Vision 2030, and the Kenya Health Policy 2014–2030. It represents a sound and evidence-based investment in Kenya's health system and the wellbeing of its people and those of the broader East African region.

The Ministry of Health, therefore, commends the East Africa Centre of Excellence in Urology and Nephrology Order, 2026 for approval and gazettement.