



REGULATORY IMPACT STATEMENT FOR THE CANCER (PREVENTION AND CONTROL) RULES, 2024

This Regulatory Impact Assessment (RIA) has been prepared by the Ministry of Health, on recommendation by the National Cancer Institute according to Sections 6 and 7 of the Statutory Instruments Act (No. 23 of 2013).

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Abbreviations

AMREF	African Medical and Research Foundation
CHMTs	County Health Management Teams
FCTC	Framework Convention on Tobacco Control
GBD	Global Burden of Disease
HIV/AIDS	Human immunodeficiency virus/ acquired immunodeficiency syndrome
HPV	Human papillomavirus
IACR	International Association of Cancer Registries
IARC	International Agency for Research on Cancer
ICCs	Intersectoral Coordinating Committee
ICGC	International Cancer Genome Consortium
LMICs	Low and middle-income countries
NaCaRe- KE	National Cancer Registry of Kenya
NCCS	National Cancer Control Strategy
NCDs	Non-communicable diseases
NCI-K	National Cancer Institute – Kenya
NGOs	Non-governmental Organizations
NHIF	National Health Insurance Fund
RECs	Research Ethics Committees
RIA	Regulatory Impact Assessment
RIS	Regulatory Impact Statement
TWG	Technical Working Groups
WHO	World Health Organization

CHAPTER I

INTRODUCTION AND BACKGROUND

1.1. SCOPE OF THE REGULATORY FRAMEWORK

The Cancer (Prevention and Control) Rules 2024 (the “Proposed Rules”) are made under Section 36 of the Cancer Prevention and Control Act, 2012. The Act provides that the Cabinet Secretary may, on the recommendation of the National Cancer Institute, make rules for the better carrying out of its functions under the Act. The Proposed Rules are intended to give full effect to the Act, and their scope is to:

- a) Set out the minimum requirements for public awareness and education on Cancer Prevention and Control;
- b) Provide measures to promote screening and early detection;
- c) Set forth comprehensive measures on standardization of care in the management and treatment of cancer; and
- d) Establish data management, safety and quality assurance in research and innovation for cancer.

1.2. REQUIREMENTS OF THE STATUTORY INSTRUMENTS ACT, 2013

Under Sections 6 and 7 of the Act, if a proposed statutory instrument is likely to impose significant cost in part of the community, or part of the community, the regulation-making authority shall, before making the statutory instrument, prepare a Regulatory Impact Statement that contains:

- a) a statement of the objectives of the proposed legislation and the reasons for them;
- b) a statement explaining the effect of the proposed legislation, including - in the case of a proposed legislation to amend an existing statutory instrument - the effect on the operation of the existing statutory instrument;
- c) a statement of other practicable means of achieving those objectives, including other regulatory as well as non-regulatory options;
- d) an assessment of the costs and benefits of the proposed statutory rule and of any other practicable means of achieving the same objectives;

- e) the reasons why the other means are not appropriate;
- f) any other matters specified by the guidelines;
- g) a draft copy of the proposed statutory rule.

Section 5 of the Act requires that a regulation-making authority conducts public consultations drawing on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument and ensuring that persons likely to be affected by the proposed statutory instrument are given adequate opportunity to comment on its proposed content.

1.3. REGULATORY IMPACT ASSESSMENT

Regulatory Impact Assessment (RIA) is a systematic policy tool used to examine and measure the likely benefits, costs and effects of new or existing regulations or rules. Its output is an analytical report that acts as an aid to decision-making. A typical RIA includes an evaluation of possible alternative regulatory and non-regulatory approaches with the overall aim of ensuring that the final selected regulatory approach provides the greatest net public benefit. Typically, the structure of the RIA should contain the following elements:

- (a) title of the proposal;
- (b) the objective and intended effect of the regulatory policy;
- (c) an evaluation of the policy problem;
- (d) consideration of alternative options;
- (e) assessment of the options' impact and distribution;
- (f) The results of public consultation;
- (g) compliance strategies, and
- (h) processes for monitoring and evaluation¹

The RIA is prepared before a new government regulation is introduced to provide a detailed and systematic appraisal of the potential impact of a new regulation and assess whether it is likely to

¹ Regulatory Policy Division Directorate for Public Governance and Territorial Development: Building an Institutional Framework for Regulatory Impact Analysis (RIA): Guidance for Policy Makers. OECD, 2008

achieve the desired objectives. An Assessment promotes evidence-based policymaking as new regulations or rules typically lead to numerous impacts that are often difficult to foresee.

From a societal viewpoint, an impact assessment should confirm whether a proposed regulation is welfare-enhancing, in that, the benefits will surpass costs. Therefore, it has objectives of improving understanding of the real-world impact of regulatory action, including both the benefits and the costs of action, integrating multiple policy objectives, improving transparency and consultation; and enhancing governmental accountability.

1.4 HISTORY OF CANCER PREVENTION AND CONTROL IN KENYA

Cancer has been a health concern in Kenya since long before the country gained independence in 1963 (it may not have been well-documented or understood early on). However, during the pre-independence era, cancer control efforts were minimal, primarily due to the limited healthcare infrastructure and resources. The primary focus was on infectious diseases, maternal and child health, and other immediate health challenges. Traditional medicine and healers often played a significant role in addressing health issues, including cancer. After gaining independence, Kenya made efforts to improve its healthcare system.

In the 1970s and 1980s, the country began addressing non-communicable diseases, including cancer, albeit with limited success. During this period, cancer awareness was almost nonexistent among the general population, and many cases went undiagnosed until they reached advanced stages.

Now, non-communicable diseases (NCDs) are the leading cause of morbidity and mortality globally, responsible for more deaths than all other causes combined. The burden of cancer has been increasing for the past few decades with the number of new cases expected to rise by about 70% over the next two decades. It is estimated that 9.1 million deaths occur globally annually due to cancer, constituting 16.7% of total global mortality. In Kenya, NCDs account for more than 50% of total hospital admissions and over 55% of hospital deaths. Cancer is the second leading NCD after cardiovascular diseases, accounting for 7% of the total national mortality, thereby making it a public health concern.

Cancer is the third leading cause of death in Kenya after infectious diseases and cardiovascular diseases. According to GLOBOCAN estimates in 2020, against a population of 53,771,300, the annual incidence of cancer was 42,116, with 27,092 deaths and the number of prevalence cases (5-year) at 82,620. This was reported as 54,156 cases among men and 28,464 cases among women.²

The five most common cancers in Kenya are: breast, cervical, prostate, oesophageal, and colorectal. Women are disproportionately affected by cancer with a higher incidence recorded in women as compared to men. The risk of developing cancer before the age of 75 years in Kenya is 18% among women and 14.3% among men. The current trends projections indicate that there will be an estimated 58,000 new cancer cases in Kenya in the year 2028, increasing to an estimated 95,217 incident cases by 2040 due to population growth, increased life expectancy, urbanization, and increase in risk factors for cancer.

1.5 INTERNATIONAL CONTEXT

In 2015, cancer caused 8.8 million deaths globally, making it the second leading cause of death after cardiovascular disease. Most of the deaths resulting from cancer occur in middle- and low-income countries (WHO, 2019). Tobacco use is the major drug-based risk factor for cancer and is responsible for about 22% of cancer deaths.

Globally, the cancer burden is rising, exerting significant strain on populations and health systems at all levels of income. There are concerted efforts towards enhancing access to comprehensive cancer prevention and control initiatives. The United Nations ‘Agenda for Sustainable Development’ calls for a reduction by one-third of premature mortality from non-communicable diseases, including cancer.

The international history of cancer prevention and control is a vast and complex topic that spans many decades. It involves the efforts of various organizations, researchers, and governments around the world to understand and combat cancer.

² National Cancer Control Strategy 2023-2028

Below is an overview of the key milestones and initiatives in the international history of cancer prevention and control:

(a) Formation of International Organizations

The World Health Organization (WHO) and the International Agency for Research on Cancer (IARC) have played crucial roles in promoting cancer prevention and control globally. Established in 1948, the WHO has been instrumental in coordinating efforts to address cancer on a global scale. The IARC, founded in 1965, focuses on cancer research and provides evidence-based recommendations for cancer prevention.

(b) Tobacco Control

Tobacco use is a major risk factor for various types of cancer. The Framework Convention on Tobacco Control (FCTC), a treaty negotiated under the auspices of the WHO, was adopted in 2003. It aims to reduce tobacco consumption through measures such as raising awareness, implementing smoke-free policies, and increasing taxes on tobacco products.

(c) Cancer Screening Programs

Screening for cancer can help detect it at an early stage when treatment is more effective. Several countries have implemented national cancer screening programs to detect breast, cervical, and colorectal cancers. These programs typically involve regular screenings for eligible individuals and follow-up care for those with abnormal results.

(d) HPV Vaccination

Human papillomavirus (HPV) is a major cause of cervical cancer, as well as other cancers. Vaccination against HPV has been introduced in many countries as a preventive measure.

(e) Cancer Registries

Cancer registries are databases that collect information about cancer cases, including incidence, mortality, and survival rates. They play a crucial role in monitoring cancer trends, evaluating prevention strategies, and facilitating research. The International Association of Cancer Registries (IACR) promotes the development and use of cancer registries worldwide.

(f) Global Cancer Control Plans

The WHO has developed global cancer control plans to guide countries in implementing effective cancer prevention and control strategies. The Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020 includes targets for reducing premature deaths from cancer, improving access to cancer care, and promoting healthy lifestyles.

(g) Research and Collaboration

International collaboration in cancer research has led to significant advancements in understanding the causes, prevention, and treatment of cancer. The International Cancer Genome Consortium (ICGC) and the Global Burden of Disease (GBD) study are examples of global initiatives that aim to improve cancer prevention and control through collaborative research.

1.6 DOMESTIC CONTEXT

Cancer is the third leading cause of morbidity, after infectious and cardiovascular diseases (Korir et al., 2016), causing 7% of deaths in Kenya per year, with 60% of Kenyans suffering from cancer being younger than 70 years old. The leading cancers in women are breast cancer (34 per 100,000 people) and cervical cancer (25 per 100,000) while in men, prostate (17 per 100,000) and esophageal (9 per 100,000) are the most common. Due to factors such as a lack of awareness, inadequate treatment and diagnostic facilities, high cost of treatment and high poverty index (Daniel, 2021), cancer in Kenya is often diagnosed when it has already spread to other areas of the individual's body.

The Kenyan Government is committed to providing accessible, affordable, quality and equitable health care for all without predisposing them to financial hardship through Universal Health Coverage (UHC). The Bottom-up Economic Transformation Agenda, 2022-2027 promotes a focus on '*Afya Bora Mashinani*', which aims to provide comprehensive cancer prevention and control strategies that emphasize early detection, improved treatment, public awareness, and a commitment to reducing cancer-related morbidity and mortality.

Like other health functions, cancer care is delivered in the context of a devolved system of governance established by the Constitution of Kenya 2010. The National Government is responsible for health policy, capacity building, national referral health facilities and technical assistance to counties, while county governments are largely responsible for health service delivery, promotion of primary health care, licensing and control of undertakings that sell food to the public, among other functions.

The cancer burden in Kenya is not uniformly distributed and may be seen to follow a pattern; various counties have a higher burden in certain areas. This implies that cancer control interventions and research, where possible, need to be aligned with local and regional priorities. Also, the cancer burden profile is different for different counties and regions and some cancer types have been noted to cluster around certain geographical areas.³

Health service delivery in Kenya is organized into 4 tiers:

- ❖ **Tier 1:** Community Health Services
- ❖ **Tier 2:** Primary Care (Dispensaries and Health Centers)
- ❖ **Tier 3:** Secondary referral (County Hospitals)
- ❖ **Tier 4:** Tertiary (National Referral Hospitals)

Kenya's first cancer treatment, control, and prevention policy was developed in 2011, quickly followed by the 2012 Cancer Act governing the establishment of a National Cancer Institute and the decentralization of prevention and treatment activities throughout the counties. Further, the National Guidelines for Cancer Management were created in 2013, cumulatively rounding out the early policy documents and actions that laid the framework for addressing Kenya's cancer burden.

In 2015, Kenya's public health insurer, the National Health Insurance Fund (NHIF), initiated coverage of up to Kshs. 5,000,000 (approx. US\$50,000) for patients with cancer who needed urgent treatment outside the country. In October 2016, NHIF reviewed the policy to include cancer treatment within the country as a way of reducing long wait times in NHIF-participating hospitals.

³ National Cancer Control Strategy 2023-2028

In March 2017, Kenya's Ministry of Health held a cancer stakeholder consultative group meeting to draft the 2017 – 2022 National Cancer Control Policy.

The growth of cancer cases in Kenya over the past decade has resulted in legislative actions and policies to guide the delivery of cancer testing and treatment services, including the development of the country's first strategic plan for cancer — Kenya National Cancer Control Strategy: 2011–2016 — by the state departments of Public Health and Sanitation and Medical Services in 2011. The guidelines identified available national resources and infrastructure while advocating for increased investments to improve cancer services. These efforts were followed by the establishment of a legal framework to support cancer services through legislative action — the Cancer Prevention and Control Act, 2012. They laid the framework for the establishment of the National Cancer Registry and the National Cancer Institute – Kenya (NCI-K). In 2015, the Cancer Act of 2012, was amended to include the County Cancer Prevention and Control Committees and renamed the Cancer Prevention and Control (Amendment) Act, 2015.

1.7 INSTITUTIONAL FRAMEWORK

The Kenya Cancer Policy 2019-2030 outlines two levels of coordination for cancer prevention and control in Kenya:

- a) National level:** National-level cancer control coordination is through the Non-Communicable Diseases Intersectoral Coordinating Committee (NCD-ICC) and the National Cancer Technical Working Group represented at the NCD-ICC. The NCD-ICC brings together actors from other sectors, given the multisectoral nature of NCDs, and is composed of several Technical Working Groups (TWG) including a cancer TWG (see Figure 6). The National Steering Committee on Cancer Prevention and Control is one of the committees to be housed at the National Steering Committee on NCDs.
- b) County-level:** At the county level, cancer prevention and control is domiciled under the multi-sectoral Non-Communicable Diseases Technical Working Groups, spearheaded by County NCD Coordinators. Dedicated cancer control focal points oversee the implementation of cancer control activities. In health facilities, cancer services are integrated with other services as per the Kenya Essential Package for Health.

Currently, Kenya has limited trained personnel in the management of cancer. As of May 2023, there were 71 cancer centers designated across 22 counties to diagnose and treat the disease, which include Six (6) comprehensive cancer centers, sixteen middle-level cancer centers, and fifty basic cancer centers.

The different institutions involved in cancer prevention, control, treatment, and management are:

i. Ministry of Health

It is charged with the responsibility of developing the overarching national policies for the coordination, funding and clarification of roles and responsibilities for health including cancer prevention and control.

ii. The National Cancer Institute of Kenya (NCI-K)

The National Cancer Institute of Kenya was established in 2012 to promote public awareness about the causes, consequences, and methods of prevention and control of cancer. The institute is to extend to every person with cancer full protection of his human rights and civil liberties by guaranteeing the right to privacy of the individual and outlawing discrimination in all its forms and subtleties. The institute positively addresses and seeks to eradicate conditions that cause and aggravate the spread of cancer by ensuring sustainable capacity for the prevention and control of cancer. The institute ensures the provision of basic health care and social services and promotes -

- utmost safety and universal precautions in practices and procedures that relate to the treatment of cancer; and
- access to quality and affordable diagnostic and treatment services for persons with cancer.

Functions of the National Cancer Institute of Kenya

According to the Act, the functions of the Institute shall be to—

- (a) advise the Cabinet Secretary on matters relating to the treatment and care of persons with cancer and to advise on the relative priorities to be given to the implementation of specific measures;

- (b) encourage and secure the establishment of hospitals, vocational treatment and care centers and other institutions for the welfare and treatment of persons with cancer in all counties of the Republic;
- (c) encourage and secure the provision of diagnostic, treatment, rehabilitation and other medical care to persons with cancer in those institutions;
- (d) co-ordinate services provided in Kenya for the welfare and treatment of persons with cancer and implement programs for vocational guidance and counselling;
- (e) collect, analyze and disseminate all data useful in the prevention, diagnosis and treatment of cancer;
- (f) collaborate with international institutions to collect (for the Register) and catalogue, store and disseminate the results of cancer research undertaken in any country for the use by any person involved in cancer research in any country;
- (g) establish and support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials;
- (h) ensure that accurate figures of persons with cancer are obtained in the country for purposes of planning;
- (i) provide access to available information and technical assistance to all institutions, associations and organizations concerned with the welfare and treatment of persons with cancer, including those controlled and managed by the Government;
- (j) encourage and secure the care of persons with cancer within their communities and social environment;
- (k) establish and support measures that seek to eradicate conditions that cause and aggravate the spread of cancer.
- (l) recommend measures to prevent discrimination against persons with cancer;
- (m) generally, to carry out measures for public information on the rights of persons with cancer and the provisions of this Act; and
- (n) encourage and participate in the provision of training on cancer prevention and control.

iii. National and Regional Cancer Centers

Effective cancer management requires a highly trained and qualified workforce, robust referral pathways and efficient health information systems with collaboration among facilities at all levels of care (including primary and secondary levels).

As of 2023, there were six comprehensive cancer(*offering cancer management and training*) treatment centers in the country (3 public, 3 private) with 58 oncologists and 11 medical physicists.

iv. County Governments

County governments are responsible for providing healthcare services within their jurisdictions, including cancer prevention, diagnosis, treatment, and palliative care. This includes ensuring that healthcare facilities have the necessary equipment, medication, and trained personnel to provide cancer-related services. As such, county governments are to:

- (a) Implement national cancer prevention and control policies, strategies and guidelines.
- (b) Provide adequate infrastructure, equipment and commodities for screening, diagnosis treatment, palliative care and survivorship services.
- (c) Provide and appropriately deploy adequate qualified personnel for cancer service delivery.
- (d) Mobilize and allocate adequate financial resources for cancer prevention and control.
- (e) Integrate cancer prevention and control into the broader county health sector plans and establish county cancer control programs.
- (f) Forge appropriate multi-sectoral partnerships at the county level.
- (g) Collect and report cancer data in the Kenya Health Information System (KHIS) and support cancer registries.

CHAPTER 2

OBJECTS OF THE CANCER (PREVENTION AND CONTROL) RULES, 2024

2.0 INTRODUCTION

Cancer is one of the four major non-communicable diseases (the others being cardiovascular diseases, diabetes and chronic respiratory diseases) that cause over 60% of global mortality annually. It is multifaceted and a challenging disease, with an estimated 10 million deaths attributable to cancer recorded annually. Of these, about 75% occur in low and middle-income countries (LMICs).

In Kenya, cancer's impact on population health and development is inextricably linked to reduced productivity, unemployment, labour loss, and capital investment reductions. The Proposed Rules will provide a structured approach to address various challenges concerning cancer prevention and control.

2.1 JUSTIFICATION FOR THE REGULATORY FRAMEWORK

The regulation applied to Cancer Prevention and Control is motivated by the desire to ensure adequate and targeted protection to the public. In doing so, the Government acknowledges that:

- (a) Patients diagnosed with cancer are more vulnerable when seeking treatment, and hence their interests need to be protected.
- (b) Appropriate rules and Regulations are essential to ensure minimum standards of safety and the provision of quality care for Cancer Prevention and Control.
- (c) Safety-related incidents or issues that produce adverse patient outcomes do occur and there is a need for the National Cancer Institute to be aware.
- (d) There are benefits to the community in ensuring high-quality cancer care.
- (e) There are market failures in cancer prevention and control that warrant intervention. Some examples, as they pertain to Cancer Prevention and Control in the healthcare sector, include:

- i. Addressing information and power asymmetries in the dissemination of cancer information within the health care system.
 - ii. Patients rely on healthcare practitioners to provide them with the information required before making decisions that are in their best interests. During this time of vulnerability, they may be unable, or uncomfortable in accessing additional information about treatment options and alternative providers.
 - iii. Addressing public health and safety is the duty of all key stakeholders in cancer prevention and control. There is an expectation in the community that the Government has a role in ensuring minimum standards of safety and quality in health care.
- (f) The Government has an interest in a high-quality, strong healthcare sector to reduce the risks associated with cancer. Presently, the number of negative consequences attributed to this disease include:
- i. loss of life ;
 - ii. decreased quality of life;
 - iii. longer-term or additional treatment;
 - iv. longer-term care and rehabilitation;
 - v. the financial impact on patients, families and careers
 - vi. cost of investigations and inquiries; and
 - vii. cost of legal action and negligence claims.

The data provided in this RIS the Government's intervention in ensuring Cancer Prevention and Control both in the public and private health care setting. The proposed interventions espoused under the Proposed Rules seek to ensure minimum standards of patient safety for diagnosed cancer patients and quality are met.

2.2 OBJECTIVE OF THE RULES

The primary objective of these Rules is to provide for the safety and quality of care for patients diagnosed with cancer. The rules prescribe:

- (i) the minimum requirements for public awareness and education on Cancer Prevention and Control;
- (ii) measures to promote screening and early detection;
- (iii) measures on standardization of care in the management and treatment of cancer; and
- (iv) data management, safety and quality assurance in research and innovation for cancer.

The secondary objective of the Rules is to prescribe fees, forms and other matters required to be prescribed under the Cancer Prevention and Control Act. These provide the mechanisms by which establishments can meet their requirements under the current Act. There are specific objectives concerning certain parts of the proposed Rules detailed in the table below.

Table 1: Specific objectives of the proposed Rules

	AREA OF REGULATION	OBJECTIVE
Cancer Prevention and Control (Standards of Care) Rules, 2024	Minimum standards of care to be adhered to by medical institutions in the treatment of cancer patients.	Set forth comprehensive rules for cancer care in Kenya. These rules encompass various aspects of cancer prevention, screening, treatment, and patient care. Enhance the quality of cancer care in Kenya, ensuring that patients receive timely and evidence-based treatments while prioritizing their safety and well-being throughout the cancer care continuum.
Cancer Prevention and Control (Inspection and Licensing) Rules, 2024	Registration and certification	Provide for designation and certification of cancer centres in the country.
Cancer Prevention and Control (Public Awareness and Education) Rules, 2024	Public awareness	Regulate cancer messaging, information dissemination, educational material creation, and advocacy efforts.

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		Establish a regulatory framework to ensure the quality and accuracy of public awareness and education efforts in cancer care in Kenya,
Cancer Prevention and Control (Consent to Research) Rules, 2024	Standards For Consent to Cancer Research	Regulate consent procedures for cancer-related human biomedical research. Provide for the repository of reports on all cancer research conducted in Kenya
Cancer Prevention and Control (Cancer Registry) Rules, 2024	Cancer Registry	Govern cancer data collection and management, ensuring proper notifications and the operations of the national cancer registry. Standardize cancer data collection and management, ensure data accuracy, protect the confidentiality of cancer patient data, and facilitate cancer research and clinical management in Kenya.

CHAPTER 3

EVALUATION OF THE PROBLEM

3.0 IDENTIFIED CHALLENGES

Cancer, usually considered a life-threatening illness synonymous with suffering and death, has a high level of stigma in many societies. Stigma is a widespread and deep cultural concept with significant effects, dimensions, and consequences in the local context. It affects individuals, families, and even the effectiveness of public health programs. Hence, it is important to address the methods that can reduce stigma or its effects on those affected through advocacy and communication.

Kenya has established effective cancer interventions and policies that aim at mitigating barriers and establishing functional and credible systems for cancer prevention and control. However, the efforts towards cancer prevention and control are eroded by environmental factors such as the lack of provider skills; limited equipment for screening, diagnosis, and treatment; inadequate supplies; late presentation by patients; high costs of treatment by medical facilities; lack of parental awareness about cancer; poor communication by providers; scarcity of pediatric oncologic services; and poor treatment completion rates.

Provider-side barriers include a lack of staff that could diagnose malignancies and refer patients to specialists; negative provider attitudes toward patients with cancer; cultural beliefs and taboos; and personal discomfort examining patients of the opposite sex have also presented difficulties. Some of the identified challenges are discussed further.

3.1 LACK OF ADEQUATE PUBLIC AWARENESS

One of the significant challenges in cancer prevention and control in Kenya before 2012 was the lack of adequate public awareness. Many Kenyans had limited knowledge about cancer, its risk factors, and preventive measures. Consequently, most individuals did not seek early screening or treatment, leading to late-stage cancer diagnoses.

3.2 LIMITED SCREENING AND DIAGNOSTIC FACILITIES

Access to cancer screening and diagnostic facilities was restricted. Most healthcare institutions lacked the necessary equipment and trained personnel to carry out cancer screenings and early diagnosis. This resulted in delays in identifying and treating cancer cases.

3.3 INADEQUATE HEALTHCARE INFRASTRUCTURE

Kenya faces significant challenges in building and maintaining cancer healthcare infrastructure across all the counties. Currently, there are only 71 cancer centers spread across only 22 counties and most of them are concentrated within the urban regions. Moreover, many of these centers lack advanced cancer care equipment, thereby posing challenges in the provision of early diagnosis and timely treatment.

3.4 HIGH COST OF TREATMENT

Comprehensive cancer treatment is expensive and out of reach for many. Unfortunately, patients with cancer deal with high medical costs which presents a significant barrier to accessing testing and treatment services for all types of cancers. This financial barrier is a deterrent to individuals who desire to seek care, leading to worsening health outcomes. It has been discovered that patients who are covered under NHIF are more likely to complete treatment as compared with those without insurance.

3.5 INADEQUATE CANCER DATA MANAGEMENT SYSTEM

Cancer data management system plays a crucial role in tracking the incidence and prevalence of cancer, guiding policy and resource allocation. However, Kenya has a limited cancer data management system, which affects the accuracy of data on cancer prevalence and trends.

3.6 CULTURAL AND STIGMA-RELATED BARRIERS

Cultural beliefs and stigma surrounding cancer prevail across many communities. In some, cancer is considered a taboo topic, leading to delays in seeking medical help and a lack of social support for cancer patients.

3.7 LIMITED RESEARCH AND INNOVATIONS

One of the earliest examples of cancer research in Kenya was the aforementioned establishment of the Kenya National Cancer Registry (KCR) in 2001. As there was insufficient investment in cancer research programs for healthcare professionals, it hindered the development of evidence-based cancer control strategies and the capacity to provide quality cancer care.

The National Cancer Control Strategy (NCCS) was launched in 2007 as a comprehensive plan that outlines the Government's goals for cancer prevention, control, and treatment in Kenya. The NCCS includes several initiatives to improve cancer research, consent and innovation, such as the development of ethical guidelines for cancer research and the establishment of a

cancer research fund.

In recent years, there has been a growing focus on cancer research, consent and innovation. This is due in part to the increasing cancer burden, as well as the growing recognition of the importance of research in developing new and better cancer treatments.

3.8 LIMITED TRAINING

Most medical professionals in Kenya have not been trained to recognize the signs and symptoms of cancer since it is a relatively new and emerging disease. This led them to treat patients for the wrong illness which thus delayed treatment. Additionally, most oncologists are located in the capital city Nairobi, which causes many patients to have to travel far distances to get specialized care. This lack of cancer expertise in Kenya thus serves as a barrier to detection as well as proper treatment.

CHAPTER 4

LEGAL AND POLICY FRAMEWORK FOR THE PROPOSED CANCER (PREVENTION AND CONTROL) RULES, 2024

4.0 INTRODUCTION

This Chapter highlights several Acts of Parliament and policies that embody the legal framework governing the Proposed Rules. An evaluation of the legal and policy frameworks related to the Cancer Prevention and Control Rules is intended to bring out the context and legal environment within which the proposed Rules are being developed.

Regulatory processes should be structured so that all regulatory decisions rigorously respect the principles of the ‘rule of law’, complement other legal requirements and ensure statutory harmony of the entire statute book.

4.1 THE CONSTITUTION OF KENYA, 2010

The national values and principles of governance set out under Article 10 (2) of the Constitution recognize human dignity and sustainable development as binding the State when making and implementing public policy. These values are further amplified in the Bill of Rights, specifically under Article 43.

The Constitution under Article 43(1) (a) states that *“Every person has the right to the enjoyment of the highest attainable standard of health, which includes the right to health care services including reproductive health care”*. Clause (2) states that *“a person shall not be denied emergency medical treatment.”* Health Law experts also argue that indeed no one should be deprived of their health rights.

The Constitution obligates the State and every State organ to observe, respect, protect, promote, and fulfil the rights in the Constitution and to take “legislative, policy and other measures, including the setting of standards to achieve the progressive realization of the rights guaranteed in Article 43. These measures include addressing the needs of vulnerable groups within society and international obligations regarding those rights⁴. Article 21 (2) requires the State to take legislative, policy and other measures to achieve the progressive realization of the rights guaranteed in Article 43.

Schedule 4 of the Constitution assigns the mandate of health policy and technical support to the national government and health service delivery to the counties. Article 20 (5) (b) requires that in allocating resources, the State will give priority to ensuring the widest possible enjoyment of the right or fundamental freedom having regard to prevailing circumstances, including the vulnerability of groups or individuals amongst other rights. These vulnerabilities are addressed in the Constitution, which pays special attention to the health of children⁵, minorities and marginalized groups⁶, and the elderly⁷. As such, barriers to healthcare services of whatever kind should not hinder access and the Government is duty-bound to remove such barriers so that health rights are genuinely met.

4.2 THE HEALTH ACT, 2017

⁴ Article 22

⁵ Article 53(1)(c)

⁶ Article 56(e)

⁷ Article 57(d)

The Health Act provides for a health service package at all levels of the health system, which shall include services addressing promotion, prevention, curative, palliative and rehabilitation, as well as physical and financial access to health care. It also provides for interventions to reduce the burden imposed by NCDs, including physical activity, counter the excessive use of alcoholic products and the adulteration of such products, reduce the use of tobacco, and promote the supply of safe foodstuffs.

4.3 THE CANCER PREVENTION AND CONTROL ACT OF 2012

The Cancer Prevention and Control Act of 2012 marked a significant turning point in Kenya's efforts to combat cancer. The legislation was a response to the growing cancer burden and the recognition of the need for a comprehensive and coordinated approach to prevention and control. The Act aimed to address the challenges that had plagued cancer control efforts in Kenya for decades.

Key provisions of the Cancer Prevention and Control Act of 2012 included:

1. **Establishment of the National Cancer Institute:** The Act created the National Cancer Institute (NCI), responsible for coordinating and implementing cancer control programs. The NCI was tasked with developing a national cancer control strategy, promoting research, and enhancing public awareness.
2. **Access to Treatment and Care:** The Act emphasized the importance of equitable access to cancer treatment and care. It called for the establishment of cancer treatment centers across the country to ensure that cancer patients, regardless of their location, had access to essential services.
3. **Preventive Measures:** The Act encouraged cancer prevention initiatives, including public education campaigns, tobacco control, and efforts to reduce cancer risk factors. It recognized the importance of early detection and diagnosis.
4. **Patient Rights and Support:** It highlighted the rights of cancer patients, including access to information, confidentiality, and protection against discrimination. The Act also called for the provision of psychosocial support services for cancer patients and their families.

5. **Cancer Registries:** The Act emphasized the need for comprehensive cancer registries to collect and analyze data on cancer incidence, prevalence and outcomes. This data would guide cancer control policies and resource allocation.
6. **Research and Training:** The Act promoted cancer research and the training of healthcare professionals in cancer care. It recognized the importance of evidence-based practice in cancer control.
7. **Funding and Resource Allocation:** The Act provided a legal framework for funding cancer control activities and resource allocation. It aimed to ensure that adequate resources were allocated to cancer prevention, screening and treatment.

4.4 OTHER RELEVANT LEGISLATIONS

These include the Tobacco Control Act, Cap 245A; The Occupational Safety and Health Act Cap 236A; The Food, Drugs and Chemical Substances Act Cap 254; Public Health Act Cap 242; the Radiation Protection Act, Cap 243; Environmental Management and Coordination Act, Cap 387; National Environmental Management and co-ordination Act Cap 387Act, and The Occupational Safety and Health - Medical Examinations Rules (Legal Notice 24 of 2005).

4.5 VISION 2030

Kenya's Vision 2030 is the long-term development blueprint expected to transform the country into a rapidly industrializing middle-income nation enjoying a high quality of life by the year 2030. The Vision, which is being implemented through successive five-year medium-term plans, aims to create a cohesive, equitable and just society based on democratic principles and issue-based politics grounded on the existing rich and diverse cultures and traditions.

The Social Pillar in Vision 2030 singles out education and training as the vehicles that will drive Kenya into becoming a middle-income economy. The Republic, therefore, requires an education system that will produce citizens who can engage in lifelong learning, learn new things quickly, perform more non-routine tasks, become capable of more complex problem-solving, take more decisions, require less supervision, assume more responsibility, and as vital tools to these ends, have better reading, quantitative, reasoning and expository skills.

4.6 THE KENYA CANCER POLICY 2019-2030

The Kenya Cancer Policy 2019-2030 provides for a framework to comprehensively address cancer control in Kenya through the systematic implementation of evidence-based interventions for prevention, screening, timely diagnosis, treatment, survivorship and palliative care, financing, monitoring, and research. It is meant to guide all stakeholders in cancer control, including government ministries, departments and agencies, county governments, faith-based organizations, private sector players, patient groups, civil society organizations and development partners, among others, towards a coordinated response.

4.7 KENYA HEALTH POLICY 2014-2030

Cancer is mainstreamed in the Kenya Health Policy 2014-2030 which demonstrates the sector's commitment under the government's stewardship to ensure attainment of the highest possible standards of health in a manner responsive to the population's health needs. The policy gives direction towards halting and reversing the rising burden.

4.8 THE MINISTERIAL STRATEGIC PLAN 2014-2018

The Ministerial Strategic Plan 2014-2018 has cancer as one of the main NCDs of focus. It addresses health promotion and health education, tobacco control, and nutrition policy including the promotion of healthy diets and physical activity, cancer control policy, and screening for NCDs, including cancer.

4.9 THE KENYA NATIONAL NCD STRATEGIC PLAN 2015-2019

The Kenya National NCD Strategic Plan 2015-2019 is the first strategic plan that addresses NCDs in the country and is adapted from the Global NCD Action Plan. Cancer is one of the priority NCDs targeted for prevention and control in the document.

4.10 THE NATIONAL CANCER CONTROL STRATEGY 2017-2022

The National Cancer Control Strategy 2017-2022 adopts a holistic approach that caters for the entire cancer continuum from prevention to monitoring and evaluation.

4.11 NATIONAL NON-COMMUNICABLE DISEASES STRATEGIC PLAN 2021/22 TO 2025/26

The NCD Strategic Plan 2021/22 to 2025/26 identifies cancer as one of the four major NCDs in terms of disease burden and economic impact in Kenya. The Strategy singles out two cancer indicators (cervical cancer screening and HPV immunization) as part of key NCD impact indicators. The Strategy also outlines interventions to reduce risk factors, including tobacco use, harmful use of alcohol, unhealthy diets and physical inactivity.

4.12 THE KENYA UNIVERSAL HEALTH COVERAGE POLICY 2020- 2030

The implementation of Universal Health Coverage (UHC) in Kenya will adopt a primary healthcare-oriented (PHC) approach to service provision. PHC providers play an essential role in cancer control through the provision of prevention, screening, early diagnosis, and referral services in an accessible, timely, appropriate manner, as well as providing ongoing care and connection between the community and secondary/tertiary levels of the healthcare system.

Therefore, investments in primary health care, including those in infrastructural, commodities and supplies, service delivery and information management should integrate relevant cancer prevention, screening and early diagnostic interventions. In Kenya, the primary healthcare (PHC) framework stipulates that the sub-county hospital will function as the “hub” in the provision of primary healthcare, thereby providing an opportunity to leverage the PHC framework for cancer-specific interventions.

4.13 NATIONAL CANCER-SPECIFIC GUIDELINES AND ACTION PLANS

- National Cancer Screening Guidelines, 2018
- National Cancer Treatment Protocols, 2019
- National Guidelines for Establishment of Cancer Management Facilities, 2019
- National Cancer Specimen Handling Guidelines, 2020
- Breast Cancer Action Plan 2021-2025.

CHAPTER 5

AN OVERVIEW OF THE PROPOSED CANCER (PREVENTION AND CONTROL) RULES

The Proposed Rules will bring to effect Section 36 of the Cancer Prevention and Control Act, 2012, and provide for the following salient features:

5.1. THE CANCER PREVENTION AND CONTROL (STANDARDS OF CARE) RULES, 2024

Kenya has made significant strides in establishing standards of care in recent years, driven by efforts from the Government, non-governmental organizations, and the private sector. A notable milestone in this endeavor was the passage of the Health Act in 2012. This legislation establishes professional health regulatory bodies responsible for setting standards of care for healthcare professionals and for disciplining those who fail to meet those standards.

In 2015, the Health Act was amended to include County Health Management Teams (CHMTs). The CHMTs are responsible for developing and implementing health policies and programs at the county level. They also have a role to play in ensuring that healthcare providers in their counties meet the standards of care set by the KMPDB.

The Government has also supported several initiatives to improve standards of care in Kenya. In 2016, the Ministry of Health launched the "Quality Care for All" campaign, which aims to raise awareness of the importance of quality care and to promote the adoption of quality improvement practices in healthcare organizations.

Non-governmental organizations (NGOs) have played a significant role in improving standards of care. The African Medical and Research Foundation (AMREF), for example, has launched many initiatives to improve the quality of care. The private sector has also been involved. For example, the Kenya Hospital Association has developed a set of standards for private hospitals in Kenya. Despite these efforts, there is still a lot of work to be done in terms

of harmonizing and improving standards of care in Kenya. The burden of disease is increasing in the country, and many people still do not have access to quality care.

The proposed Cancer Prevention and Control (Standards of Care) Rules, 2024, set forth comprehensive rules for cancer care in Kenya. These rules encompass various aspects of cancer prevention, screening, treatment, and patient care. The object of these Rules is to give effect to the provisions of the Cancer Prevention and Control Act by;

- a) providing for the requirements for the establishment of cancer centers ;
- b) establishing the minimum standards in cancer management including standards for medical equipment, infrastructure and human resources; and
- c) providing for the procedures of categorization of cancer centers in the provision of cancer care services.

The Rules strive to ensure compliance with the best practice standards for cancer care, overseeing cancer management practices, guiding patient education, and ensuring competency among oncology personnel. They also detail the establishment and operation of cancer centers, emphasizing multidisciplinary care, timely diagnosis, and adherence to evidence-based protocols.

Every cancer center shall where necessary appoint a Multi-disciplinary Tumor Board which shall be responsible for the management of cancer patients in a consultative approach. They also emphasize on patient involvement and informed decision-making, the rules mandate specific protocols for diagnostic imaging, pathology, nuclear medicine, radiation oncology, surgery, nursing, chemotherapy, palliative care, and survivorship programs, all with a focus on patient-centered care. All cancer centers shall always provide palliative care from the point of cancer diagnosis and throughout the course of illness.

The rules address various other aspects of cancer care, such as infection prevention, occupational health and safety, waste management, emergency medical care, and adverse event reporting. They emphasize the importance of protecting both the public and healthcare workers from potential hazards associated with cancer care.

Additionally, the rules provide the standards for consent to Cancer Research. Individuals planning to undertake cancer-related research in Kenya will be required to submit a request for review that includes a detailed research proposal, including participant roles, risks, benefits, confidentiality, compensation for injuries, and other relevant information. Researchers are required to submit informed consent forms from participants. Upon completion of the research, a copy of the research findings shall be shared with the institute.

For cancer-related clinical trials; medical institutions shall obtain informed consent from cancer patients. If research is involved, the prescribed consent procedure will be followed. The development of informed consent for research in Kenya reflects a transition from minimal ethical considerations to a landscape deeply influenced by international guidelines, national rules, and ethical principles.

These rules aim to enhance the quality of cancer care in Kenya, ensuring that patients receive timely and evidence-based treatments while prioritizing their safety and well-being throughout the cancer care continuum as well as protect the rights and well-being of cancer research participants and ensure ethical research practices in Kenya.

On transitional provisions; the rules Provided that the health facility offering any cancer care services, shall within two (2) years after commencement of these Rules, put in place measures to ensure compliance with the provisions of the Rules, failure to which such health facility offering any cancer care services, shall automatically cease to be offering any cancer care services.

5.2. THE CANCER PREVENTION AND CONTROL (INSPECTION AND CERTIFICATION) RULES, 2024

In early 2000, the Ministry of Health and Kenya Bureau of Standards (KEBS) began developing guidelines for the establishment of cancer treatment facilities emphasizing the importance of inspection to ensure the quality of care.

In recent years, the Kenya Medical Practitioners and Dentists Council (KMPDC), has supported the accreditation and certification of cancer centers, with Kenyatta National Hospital's Cancer Treatment Center (CTC-KNH) and the Moi Teaching and Referral Hospital's Cancer Center accredited as Centers of Excellence.

There is a need to incorporate inspection and certification of cancer centers within the devolution of cancer care services to the county governments, as these underscore Kenya's commitment to providing its citizens with access to high-quality cancer care that is crucial in addressing the growing burden of cancer in the country and improving patient outcomes.

The proposed Cancer Prevention and Control (Inspection and Licensing) Rules, 2024 in Kenya outline rules for the designation and certification of cancer centers in the country. These rules are established under the Cancer Prevention and Control Act of 2012 and serve to ensure quality cancer care. The key provisions of the rules include:

1) Establishment of Inspections and Licensing Committee

An Inspection and Licensing Committee is established to oversee the licensing of cancer centers. The Committee is composed of eight members appointed by the National Cancer Institute of Kenya, including the chief executive officer. It has various responsibilities, among them issuing licenses, inspecting cancer centers, and maintaining a register of licensed centers.

2) General Practice for Cancer Centers

The Institute encourages the establishment of cancer centers in all counties of Kenya to provide treatment and care for cancer patients.

3) Eligibility for Practice

Entities intending to operate a cancer center must ensure that the premises have been pre-licensed by the Medical Practitioners and Dentists Council and have been inspected and approved by the National Cancer Institute.

4) *Compliance certificate*

Cancer centers must apply for a compliance certificate, accompanied by the required fee. The certificate is issued following a full inspection to ensure compliance with minimum requirements. Compliance certificates are subject to conditions, and a center may not operate more than two clinics under one license. Certificates are valid for 12 months and renewable thereafter.

5) *Inspections*

All cancer centers, whether standalone or in hospitals, are subject to inspection by the Institute, which designates facilities based on their compliance with specific levels set out in the rules.

6) *Inspection Teams*

Inspection teams consist of professionals with expertise in key service areas relevant to cancer management.

5.3. THE CANCER PREVENTION AND CONTROL (INFORMATION, EDUCATION AND COMMUNICATION) RULES, 2024

In Kenya, the regulatory framework on public awareness of cancer has a relatively short history, dating back to the early 2010s. However, there have been significant strides made in recent years, thanks to the efforts of the government, non-governmental organizations, and the private sector.

One of the earliest examples of regulation on cancer public awareness in Kenya was the passage of the Cancer Act in 2012. The Cancer Act established the National Cancer Institute of Kenya (NCI-Kenya) as the lead agency for cancer prevention, control, and treatment in Kenya. The Act also requires the NCI-Kenya to develop and implement a national cancer control strategy, which includes a plan for public awareness.

In 2015, the Cancer Act was amended to include County Cancer Prevention and Control Committees. These Committees are responsible for developing and implementing cancer

prevention and control. In 2016, the Ministry of Health launched the "Cancer: Know It, Beat It" campaign, which aimed to raise awareness of the causes, symptoms, and prevention of cancer activities at the county level.

The proposed Cancer Prevention and Control (Public Awareness and Education) Rules, 2024 in Kenya are designed to govern cancer messaging, information dissemination, educational material creation, and advocacy efforts. The object of these Rules is to give effect to the provisions of the Act by;

- (a) creating awareness on cancer prevention;
- (b) encouraging cancer screening and early detection of cancer; and
- (c) promoting positive messaging of information relating to cancer.

These rules shall apply to the modalities of disseminating information relating to cancer and establish a regulatory framework to ensure the quality and accuracy of public awareness and education efforts in cancer care in Kenya, emphasizing the importance of accurate information, cultural sensitivity, and evaluation of materials and campaigns.

The rules provide that a person, healthcare provider, or medical institution disseminating information shall ensure that the information is objective, true, and dignified; the manner of dissemination is the information respectful of the professional ethics of the healthcare profession; does not attempt to denigrate other healthcare providers or medical institutions or the profession; and does not infringe on patient confidentiality.

These materials should be factual, truthful, and aligned with Kenya's National Policy Guidelines for cancer prevention and control. They must also use appropriate language and visuals and adhere to copyright and ethical principles.

A person who wishes to undertake a public information campaign, program, or any public education forum with information relating to cancer shall, before conducting the campaign, program, or forum, submit information to the institute for review to ensure that the information complies with the requirements in these Rules; and for provision of necessary recommendations. For those planning public information campaigns or programs, an

application should be made to the institute, providing details about communication strategies, target audience, materials, and proposed dates and venues. The Institute shall review these applications within 30 days and issue licenses accordingly.

The developers of cancer-related information, education, and communication materials are required to use simple language, visuals, and cultural appropriateness. Public information campaigns or programs are required to conduct pre-tests of their materials, which must be peer-reviewed and involve at least 20 participants.

The Institute is responsible for continuous cancer evaluation, considering factors like relevance, appeal, accuracy, and cultural appropriateness when assessing information, education, and communication materials.

5.4. THE CANCER PREVENTION AND CONTROL (MANAGEMENT OF INFORMATION ON CANCER) RULES, 2024

The history of the Kenya Cancer Registers can be traced back to the 1960s. These early efforts largely focused on collecting limited data in unstructured formats; neither was there any formal coordination in the registration processes then. The country began a collaboration with international organizations to improve its cancer documentation and registration capabilities and enhance data management practice.

The first formal cancer registry in Kenya was established at the Kenya Medical Research Institute (KEMRI) in 2001. The registry focused on the population of the then Nairobi Province (now Nairobi County). In 2016, the Ministry of Health through the National Cancer Control Programme (NCCP) established the Kenya Cancer Registry which aimed at pooling population-based cancer data and expanding the registry to more counties.

The mandate to establish the National Cancer Registry is legally provided by Section 20 of the Cancer Prevention and Control Act of 2012. Subsequently, Section 21 of the same Act obligates all medical institutions to notify the National Cancer Institute of Kenya (NCI-K) of all cancer cases within 60 days of diagnosis. It is upon this background that the National

Cancer Registry of Kenya (NaCaRe-KE) system was established. The Institute developed the National Cancer Notification Form and an electronic system to ease the notification process.

The proposed Cancer Prevention and Control (Management of Information on Cancer) Rules, 2024, give effect to the provisions of the Act by facilitating decision-making and policy formulation in the prevention, control, and management of cancer in the country.

These Rules shall apply to the procedure for the notification of diagnosis of cancer to the Institute; administration and maintenance of the National Cancer Registry; and keeping of the records of cancer patients. They aim to govern cancer data collection and management, ensuring proper notifications and the operations of the National Cancer Registry.

Medical institutions are required to submit notifications in a specified format within 60 days of diagnosing a cancer patient. A National Cancer Registry of Kenya (NaCaRe-Ke) is established to facilitate online cancer case notifications, support facility registries, manage various cancer registries in the country, analyze cancer data, and share and disseminate related information. The NaCaRe-Ke maintains a web-based repository for patient-level data and manages access rights. The National Cancer Register shall provide for;

- a) electronic notification of diagnosis of cancer;
- b) interoperability with data relating to cancer;
- c) interoperability with electronic systems;
- d) interoperability with the Comprehensive Integrated Health Information System established under section 15(1) of the Digital Health Act;
- e) collection, aggregation, and analysis of data on cancer in accordance with the Digital Health Act and the Data Protection Act; and
- f) dissemination of data on cancer.

Access to the NaCaRe-Ke is granted to various user categories, including county-level users, facility registrars, facility other users, sub-county level users, national super users, national other users, other general users, and system admins, each with specific privileges and limitations. The facility cancer registrar shall verify the medical records of cancer patients for

accuracy and completeness. A person who maliciously enters fraudulent information in the National Cancer Register or in the facility cancer register commits an offence and shall, on conviction, be liable to a penalty specified under section 35 of the Act.

Medical institutions offering cancer care services shall be inspected and licensed by the institute. All cancer centers shall employ a qualified Cancer registrar who is registered by has undergone training and certification by the institute. The registrars are responsible for managing patient records, adhering to standard operating procedures, and generating reports.

Sharing patient-level cancer data is governed by the Data Protection Act of 2019 and the Digital Health Act, of 2023 and can only occur under specific circumstances, including clinical management, legal requirements, or research with ethical considerations and patient consent. A person seeking to access information in the National Cancer Register shall make an application to the Chief Executive Officer of the National Cancer Institute.

5.6. OFFENCES AND PENALTIES

Offences and penalties are proposed to be established under these rules, with fines and imprisonment specified. The Institute shall have the power to cancel or refuse to renew compliance licenses for contraventions of these rules.

5.7 FEES AND ADMINISTRATIVE COSTS

The administrative costs of the National Cancer Institute will be funded by the National government in addition the Institute intends to collect the fees for the services rendered to facilitate the implementation and enforcement of these Rules. The fees will be charged for the inspection and registration of cancer cancers and access to data in the National data registry.

CHAPTER 6

SOCIAL ECONOMIC IMPACTS

The implementation of the National Cancer Prevention and Control Rules, 2024 can have significant socio-economic impacts across various domains in the Kenyan context. By improving public awareness, standardizing care, and ensuring professional competence, these rules can lead to better health outcomes, reduced healthcare costs, and overall economic benefits. Here's an analysis of these impacts on Information, Education, and Communication (IEC), Standards of Care, and Licensing and Certification Rules:

6.1 INFORMATION, EDUCATION, AND COMMUNICATION RULES

- a) **Increased Public Awareness and Early Detection:** Enhanced IEC efforts lead to greater public awareness about cancer prevention, symptoms, and the importance of early detection. Early detection improves survival rates, reduces treatment costs, and increases productivity by keeping individuals healthier for longer.
- b) **Health Literacy and Behavioral Changes:** Effective IEC campaigns improve health literacy, leading to healthier lifestyle choices (e.g., reduced smoking, better diet, increased physical activity). Reducing risk factors associated with cancer decreases the incidence of the disease, leading to long-term healthcare savings.
- c) **Economic Benefits from Education Campaigns:** Public health campaigns can be cost-effective by reducing the burden on the healthcare system through prevention and early intervention. Better-informed populations contribute to a healthier workforce, enhancing overall economic productivity.

6.2 STANDARDS OF CARE

- 1. **Improved Quality of Healthcare:** Implementing standardized care protocols ensures that all patients receive high-quality and consistent care, regardless of their geographic location or socio-economic status. Standardized care can lead to better health outcomes, reducing the overall economic burden of cancer treatment and improving survival rates.

2. **Reduced Healthcare Costs:** By standardizing treatment regimens and care pathways, unnecessary and redundant treatments can be minimized, leading to cost savings. Economies of scale can be achieved through bulk procurement of standardized treatment supplies and medications.
3. **Equity in Healthcare Access:** Standards of care help in bridging the gap between urban and rural healthcare facilities, ensuring equitable access to quality cancer care. This equity can result in a more balanced economic development as healthier populations in all regions can contribute to the economy.

6.3 LICENSING AND CERTIFICATION RULES

1. **Enhanced Professional Competence:** Stringent licensing and certification ensure that healthcare professionals are well-qualified and competent to provide cancer care, leading to better patient outcomes. High standards for healthcare providers can enhance the reputation of the healthcare system, attracting more investment in the healthcare sector.
2. **Regulation and Quality Control:** Consistent and rigorous certification processes maintain high standards in cancer treatment facilities and professionals, ensuring that patients receive safe and effective care. This regulation helps in maintaining public trust in the healthcare system, which is crucial for its sustainability and growth.
3. **Innovation and Research:** Clear licensing and certification guidelines encourage continuous education and training among healthcare professionals, fostering a culture of innovation and research. Investments in research and development can lead to breakthroughs in cancer treatment, offering long-term economic benefits through improved treatment modalities and reduced mortality rates.

Overall, the implementation of National Cancer Prevention and Control Rules can have profound and wide-ranging socio-economic impacts from reduction in mortality and morbidity, to healthcare system efficiency and long-term economic gains. Implementation of the Rules can significantly improve public health outcomes, foster economic growth, uphold human rights, and strengthen the healthcare system. Its successful implementation will require careful planning, adequate funding, and sustained commitment from both the public and private sectors.

Table 2: Matrix of the impact of options on key sectors

Impact on sectors	Option one: Maintaining the Status quo	Option two: Administrative measures	Option three: Developing the Digital Health Act Rules
Impact on the Public Sector	Delays in full implementation of the National Cancer Prevention and Control Act. Unregulated cancer awareness and education	Administrative measures can be implemented more quickly and adjusted more easily than formal Rules. However, this might lead to inconsistent application and uncertainty among stakeholders.	This may require increased budget allocation. Improved quality and consistency of cancer care through standardized protocols. Enhanced healthcare access in rural and underserved areas. Better training and certification for healthcare workers, improving skills and retention.
Impact on the Private Sector	The private sector will largely remain unaffected.	There is no guarantee that administrative measures will address private-sector concerns.	Private healthcare facilities (cancer centers) will need to adhere to new standards, improving care quality. Increased demand for cancer-related services and products, fostering growth in healthcare businesses. Private entities engaging in public health initiatives and

			awareness campaigns.
Economic Impact	Largely no impact.	Enforcement and assurance of quality will be a challenge	Initial investment costs are balanced by long-term savings from early detection and prevention. A healthier population leads to a more productive workforce.
Social Impact	Challenges associated with fragmented health systems and the portability of Health Data impede access to specialized healthcare services.	While administrative measures offer agility and the potential for rapid improvements in healthcare delivery, there are significant risks related to consistency, equity, and public trust.	Improved access to healthcare services across the population by promoting access to healthcare, patient empowerment, and improved quality of care.
Human Rights Impact	Attainment of socio-economic rights on the highest attainable standard of health will be slowed down.	Administrative measures do not have the force of law necessary for guaranteeing human rights.	The rules will assist in the achievement of the highest attainable standards of healthcare as well as fulfill the rights to information for citizens. Enhanced public awareness and education support individuals' rights to make informed health decisions
Impact on business	Largely no impact	Lack of the force of law for full implementation of the Act.	Provide opportunities for innovation and investment in the healthcare industry,

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			especially in cancer awareness, education and screening.
Impact on environment	Will be generally unaffected	Challenges in the enforcement of disposal of cancer-related waste.	Facilitate investment in health infrastructure leading to a better environment for all. Enforce proper disposal of medical waste from increased screenings and treatments.
Impact on taxes	Largely no impact	Largely no impact	Largely no impact. However, the rules can facilitate the efficient use of tax revenue for public health improvements, leading to long-term economic benefits.
Impact on existing legal frameworks	The existing legal gaps will not be addressed	Regulatory concerns will remain unaddressed	Provides harmony with related legal including the Digital Health Act No.15 of 2023. Enhance regulatory compliance. Strengthened legal framework supporting monitoring, evaluation, and enforcement of cancer control measures.

CHAPTER 7

COST-BENEFIT ANALYSIS FOR THE PROPOSED CANCER (PREVENTION AND CONTROL) RULES

This section seeks to assess the changes proposed by the rules in terms of their costs and benefits to justify the proposals according to Section 7(d) of the Statutory Instruments Act.

7.1. MATRIX OF BENEFITS AND COSTS OF THE PROPOSED CANCER PREVENTION AND CONTROL RULES.

The analysis of the expected costs and benefits of the proposed rules contained in this part seeks to answer the question of whether the benefits justify the costs. This would enable the Regulator to estimate the total expected cost and benefit of every aspect of the Rules. The objective of the proposed Rules is to provide for the safety and quality of care for patients diagnosed with cancer who are receiving health services and all Kenyans in fostering cancer prevention and control. In considering the benefits of the proposed Rules, the key questions to be answered include:

- 1) What is the nature and extent of information constraints faced by Kenyan citizens in the quest for cancer prevention and control?
- 2) To what extent is it the role of government to address residual safety risks given the high level of voluntary compliance with the existing Rules?
- 3) In the absence of the Rules, would other incentives be sufficient to minimize the incidence of adverse events and achieve appropriate safety outcomes?
- 4) To what extent do Rules contribute to safety outcomes?

Kenyans will benefit greatly from the Proposed Rules as these will:

- (a) promote public awareness about the causes, consequences, means of prevention and control of cancer through factual and evidence-based information on cancer;
- (b) promote access to cancer screening and early detection for timely diagnosis and treatment;
- (c) establish a national framework for the expansion of cancer treatment outcomes;

- (d) regulate the quality of cancer care, accreditation of cancer centers and infrastructure;
- (e) establish and strengthen information systems and an integrated surveillance system to monitor trends in screening, treatment, outcomes and mortality of cancer to inform policy and planning; and
- (f) promote the institutionalization of cancer prevention and control across all sectors and at all levels.

Table 3: Cost Benefits Analysis of the three options.

Option	Description	Costs	Benefits
Option One: Doing Nothing/ Maintaining Status Quo	Maintaining the status quo means that no Rules will be developed and therefore challenges facing the full implementation of the Cancer Prevention and Control Act will not be addressed.	The existing costs are fragmented into different programs in the National and County governments.	No additional funding required
Option Two: Application of Administrative Measures	Issuance of ministerial orders and circulars prescribing guidelines and administrative measures to address the identified challenges	No guarantee for full implementation of the Cancer Prevention and Control Act Lack of capacity to fully enforce the	Minimum costs as measures will be undertaken by the existing framework. Quick to implement.
Option 3: Development and Implementation of the Proposed Rules	Implementing cancer prevention and control Rules will require significant costs but will provide long-term benefits in terms of improved public health, economic savings, and improved quality of life are substantial.	Cost for the implementation of Cancer Prevention and Control Rules 2024. Establishing and maintaining cancer registries, awareness campaigns, educational programs, and healthcare facilities require	Benefits of implementation of Cancer Prevention and Control Rules 2024. Increased awareness and education can lead to early detection , significantly improving survival rates and reducing

		substantial financial investment. Training healthcare professionals and staff on new Rules, data management, and patient care standards incurs costs. Implementing and monitoring adherence to Rules necessitates a dedicated administrative framework, including hiring additional staff. Technological Investments. Compliance and Enforcement costs Regulatory Compliance to align with new standards.	treatment costs over time. Education on lifestyle changes and risk factors can lead to a reduction in cancer incidence. Implementing standardized care protocols ensures consistent and high-quality treatment across the country and professional development. Comprehensive Cancer Registries enhance evidence-based policy decisions and facilitate cancer research. Regulation of the public forums Education will ensure access to accurate information protecting the public from misinformation and stigma.
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CHAPTER 8

CONSIDERATION OF ALTERNATIVES TO THE PROPOSED CANCER (PREVENTION AND CONTROL) RULES

The Statutory Instruments Act requires a regulator 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. (Regulations or rules should be the last resort in realizing policy objectives.) The options considered under this part are maintenance of the status quo, administrative measures and development of the proposed Cancer (Prevention and Control) Rules.

OPTION ONE: MAINTENANCE OF THE STATUS QUO

The proposed Cancer (Prevention and Control) Rules are responsive to the current global health reforms. In the absence of these rules, there is no guarantee of safe, quality healthcare services to the citizens of Kenya. Citizens will continue to agitate and expect that the government will act to ensure that minimum requirements are in place. There will be no mechanism to promote management and accountability structures within healthcare agencies which encourage safety, quality, equity and efficiency in service delivery for persons diagnosed with cancer. The proposed regulatory framework specifies three categories for the designation and certification of cancer facilities for safe and high-quality care. The proposed rule supports that cancer and palliative care is consumer-centered; driven by information; and organized for safety while also identifying two critical aspects fundamental to addressing the shortages in achieving cancer prevention and control:

- 1 Underuse — failure to provide a service when it would have produced favorable outcomes.
2. Misuse — avoidable complications of appropriate health care.

By maintaining the status quo, the legal requirements under Section 36 of the Cancer Prevention and Control Act of 2012 will not be fulfilled. In addition, the challenges identified such as lack of

provider skills in the management and treatment of cancer; limited equipment for screening, diagnosis, and treatment; and supplies, late presentation by patients, high costs of treatment by medical facilities, lack of parental awareness about cancer, poor communication by providers, and scarcity of pediatric oncologic services, poor treatment completion rates and lower chances of event-free survival 2 years after treatment among others will continue. As a result, several negative consequences with social and economic costs may continue to affect individuals, the community and the health sector, including:

- (i) loss of life;
- (ii) decreased quality of life;
- (iii) longer-term or additional treatment
- (iv) longer-term care and rehabilitation;
- (v) the financial impact on patients, family and careers; and
- (vi) high cost of investigations and inquiries

OPTION TWO: ADMINISTRATIVE MEASURES

Administrative measures involve the issuance of directives and circulars to the various planning authorities. This is a non-regulatory measure which if applied, will depend on the goodwill of public officers to implement the provisions of the Cancer Prevention and Control Act 2012. Administrative measures are subjective, not binding and may be challenged in a court of law. In addition, some administrative measures were issued in the past and have not achieved the desired objectives. While the Ministry has developed standards of care guidelines, information collected by the Institute indicates that the guidelines have not been effective in ensuring quality of care. Administrative measures will not support inspections of registered establishments to give the institute some indication of the nature of the challenges in providing quality care to persons diagnosed with cancer. The Institute must use a risk-based approach in determining the frequency of inspections and evaluate the levels of risk in a health service given in cancer establishments. Inspections must be conducted against pre-established criteria, with consideration given to the potential effect of adverse events on the patient to ensure compliance.

The option of a non-regulated environment presents a risk that healthcare providers will pursue a competitive advantage that may result in decreased safety and quality. Presently, healthcare

consumers do not necessarily have sufficient information to make informed decisions about the type, quality and price of the treatment they will receive. They are predominantly reliant on the providers of health care to advise what is required and may not have the ability to ask questions or seek other options and opinions. Consumers' access to the market: the circumstances under which consumers seek health care are different from a normal market arrangement.

Moreover, there may be an urgent need for treatment and therefore no opportunity to choose providers. Limited price signals: in a standard market situation a consumer can select a product, taking into consideration the price; however, the costs of health products for cancer can be unpredictable in the health sector via insurance arrangements.

The non-regulatory approach supports a supplier-induced demand. The risk that practitioners promote the use of their services or treatments to consumers will continue without the necessary checks for specialized skills in oncology. The market-driven scenario in the arena of cancer would not enable the Government to meet its primary objective of ensuring minimum standards of safety and quality of health care for all Kenyans. In addition, the Cancer Prevention and Control Act will not be fully implemented. The government would not be able to administer the current Cancer Prevention and Control Act. In the absence of the Rules, there would still be drivers for the rights of cancer patient safety and quality. These include a review of the national standards for health care, as well as professional codes of conduct and specialist practice guidelines. While these drivers promote safety and quality, under the base case there is no power for government to act or intervene in circumstances where it is found that these requirements are not being met.

OPTION THREE: FORMULATING THE PROPOSED CANCER PREVENTION AND CONTROL RULES

The proposed Cancer (Prevention and Control) Rules will yield the following benefits:

- (a) promote public awareness about the causes, consequences, means of prevention and control of cancer through factual and evidence-based information on cancer;
- (b) promote access to cancer screening and early detection for timely diagnosis and improvement;
- (c) establish a national framework for the expansion of cancer treatment outcomes;

- (d) regulate the quality of cancer care, accreditation of cancer centers and infrastructure;
- (e) establish and strengthen information systems and an integrated surveillance system to monitor trends in screening, treatment, outcomes and mortality of cancer to inform policy and planning; and
- (f) promote institutionalization of cancer prevention and control across all sectors and at all levels.

The assessment of the cost and benefits indicates that the benefits of formulating the rules far outweigh the costs, therefore, option three was selected as the preferred option.

Annexure 1 provides a detailed analysis of the costs and benefits of the three options available in responding to the challenges in ensuring cancer prevention and control.

CHAPTER 9

PUBLIC CONSULTATIONS

9.0 LEGAL REQUIREMENTS RELATING TO PUBLIC PARTICIPATION AND CONSULTATION.

It is a constitutional requirement to carry out public participation whenever a state or public officer enacts any law or makes/implements a public policy. This requirement is based on Article 1 of the Constitution on the sovereignty principle which vests all sovereign power to the people of Kenya. This power entitles the people to access the process of making public decisions through their involvement. As such, public participation ought to be inclusive, transparent and accountable.

Article 174 gives powers of self-governance to the people, enhances their participation in the exercise of the powers of the State and in making decisions affecting them, and recognizes the rights of communities to manage their affairs and to further their development.

The Statutory Instruments Act obligates a regulation-making authority to carry out appropriate consultations before making statutory instruments (Rules) where the proposed rules are likely to have a direct or a substantial indirect effect on business or restrict competition. It further provides that in determining whether any consultation that was undertaken is appropriate, the regulation-making authority shall have regard to all relevant matters, including the extent to which the consultation:

- (a) drew on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument; and
- (b) ensured that persons likely to be affected by the proposed statutory instrument had an adequate opportunity to comment on its proposed content.

The Act also states that the persons to be consulted should be notified either directly or by advertisement through representative organizations. They shall also be invited to make submissions by a specified date, which should not be less than 14 days or be invited to participate in public hearings concerning the proposed instrument.

9.1. APPROACH AND METHODOLOGIES

The Institute opted to adopt the following methodology:

1. Publishing of the draft copy of the Cancer Prevention and Control Rules, 2024 in the NCI-K website inviting representations, generally and specifically, from the identified stakeholders.
2. Stakeholder notification on the ongoing process through letters and follow-up emails inviting them to tender their submissions on the draft Rules within a specified reasonable period.
3. Posting advertisements in newspapers of wide national circulation inviting any persons or institutions to make their submissions within a specified date and directing them on where they can get copies of the Rules.
4. Holding virtual/physical meetings with select stakeholders.
5. Requesting for written submissions on the draft rules.

9.1 INITIAL PARTICIPATION OF THE STAKEHOLDERS

To ensure nationwide public participation, the Institute carried out consultations and stakeholder engagement forums. The following stakeholders were identified and involved in the development of the proposed Rules:

- 1) All members of the public
- 2) Healthcare providers
- 3) Ministries, Departments and Agencies
- 4) County governments
- 5) Healthcare provider regulatory bodies
- 6) Healthcare professionals' associations
- 7) Patient support groups.
- 8) Religious groups
- 9) Civil societies
- 10) Media
- 11) Development partners.

9.2. THE PROCESS OF PUBLIC CONSULTATIONS

According to Section 5 of the Statutory Instruments Act⁸, the Institute identified specific stakeholders with whom it engaged in a consultative process. These include the main professional and specialist institutions and individuals directly or indirectly affected by the proposed statutory instruments⁹.

The stakeholders were invited to submit comments on the zero draft rules within a specified time through letters and emails. Feedback collection methods encompassed both physical forms and electronic submissions via email (to ria2023@ncikenya.go.ke), thereby allowing citizens to provide input through their preferred channels.

The public participation process for the Cancer Prevention and Control rules encompassed engagement activities in eight clustered regions representing the former eight provincial headquarters in Kenya. To ensure inclusivity, presentations were delivered in multiple languages, including English, Kiswahili, vernacular languages, and Kenya Sign Language, catering to the linguistic diversity of the populace. These engagements were conducted through public forums held in venues that were extensively publicized in local newspapers on 2nd April 2024 and via social media.

There was a remarkable turnout of members of the public at the public forum sessions. Approximately **830** participants took part in the exercise. Attendees comprised a diverse cross-section of society, including healthcare professionals, policymakers, community leaders, and concerned citizens. They actively engaged in discussions, expressing their opinions, concerns, and suggestions regarding various aspects of the Cancer Prevention and Control Rules. The level of participation demonstrated a genuine interest and commitment from the public to contribute to the legislative process.

⁸ Institutions from where there can be drawn knowledge of persons having expertise in fields relevant to the proposed statutory instrument and persons likely to be affected by the proposed statutory instrument.

⁹ See list of consulted institutions in the Annex.

The discussions reflected a range of perspectives on the proposed rules. While some attendees voiced support for certain provisions, others raised questions and highlighted areas of potential improvement or clarification. This diversity of viewpoints underscored the importance of inclusive dialogue in shaping effective healthcare policies.

Organizers efficiently facilitated the collection of feedback during the fora sessions, employing various mechanisms such as written submissions. This ensured that all attendees had an opportunity to express their views and provide input on the proposed rules.

The transparent and inclusive nature of the public fora process fostered trust and transparency in the legislative process. By actively soliciting public input, policymakers demonstrated a commitment to democratic principles and responsiveness to the needs and concerns of the populace.

The Institute also conducted a two-day stakeholder engagement forum with the county assembly fora in Nakuru County on the 23rd and 24th of April 2024. Subsequently, all feedback obtained from the public participation exercise was collated and analyzed, with amendments made to the Proposed Rules as applicable. The public participation report is annexed providing a summary of the sentiments during the public forum sessions. The general feedback was that the rules were generally good.

CHAPTER 10

COMPLIANCE AND IMPLEMENTATION

10.1 INSTITUTIONS

The regulator must assess the adequacy of the institutional framework and other incentives through which the regulation will take effect and design responsive implementation strategies that make the best use of them¹⁰. The implementation and enforcement of these rules will be undertaken through the existing institutional framework at the national level (Ministry of Health) and the county level (county governments).

10.2 CONCLUSION

Based on the analysis in this report, the proposed Cancer (Prevention and Control) Rules are extremely necessary. The proposed rules provide a framework for the people of Kenya to enjoy the socio-economic rights as enshrined in the Constitution. Moreover, the proposed Rules support Kenya's international commitments under the United Nations 'Agenda for Sustainable Development' which calls for a reduction by one-third of premature mortality from Non-Communicable Diseases, including cancer.

The proposed rules will reduce the cancer burden that is exerting significant strain on populations and health systems at all levels of income. The proposed rules promote access to comprehensive cancer prevention and control initiatives while offering socio-economic and legal benefits. They promote the fulfillment of Article 43(1) (a) which states inter alia that *"Every person has the right to the enjoyment of the highest attainable standard of health, which includes the right to health care services including reproductive health care"*.

10.3 RECOMMENDATIONS

From the analysis provided and the above conclusion, it is recommended that the proposed Cancer Prevention and Control Rules, 2024 be adopted.

¹⁰ Source: OECD (1995), the 1995 Recommendation of the Council of the OECD on Improving the Quality of Government Regulation, Paris.