REPUBLIC OF KENYA

MINISTRY OF HEALTH

HEALTH RECORDS MANAGEMENT AND INFORMATION MANAGERS BOARD

REGULATORY IMPACT STATEMENT FOR REGULATIONS AND RULES UNDER THE HEALTH RECORDS AND INFORMATION MANAGERS ACT, CAP. 539

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

FEBRUARY 2025

DEFINITIONS

"Board"	means the Health Records and Information Managers Board established under Section 3 of the Health Records and Information Managers Act;
"Cabinet Secretary"	means the Cabinet Secretary for the time being responsible for matters relating to health;
"Manager"	means an officer trained in health records and information and charged with the responsibility of managing health records and information for health services

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ABBREVIATIONS

AMRO-KENYA	Association of Medical Records Officers - Kenya
CPD	Continuing Professional Development
DHIS	District Health Information Software
DPA	Data Protection Act
DQA	Data Quality Assurance
EHRs	Electronic Health Records
EMRs	Electronic Medical Records
HIS	Health Information Systems
HRIM	Health Records and Information Management
ICD	International Classification of Diseases
KHIS	Kenya Health Information System
KHSSP	Kenya Health Sector Strategic and Investment Plan
KHDGF	Kenya Health Data Governance Framework
KMTC	Kenya Medical Training College
MOH	Ministry of Health
RIS	Regulatory Impact Statement
UPI	Unique Patient Identifier
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 PURPOSE OF THE REGULATORY IMPACT STATEMENT

The Health Records and Information Managers Board is established by an Act of Parliament, the Health Records and Information Managers Act (Training, Registration and Licensing) Act no. 15 of 2016.

The Health Records and Information Managers Act (hereinafter referred to as the "Act") provides a framework for standardizing and regulating health records and information training and practice in Kenya.

It is worth noting that before the appointment of the HRIM Board, the Association of Medical Records Officers-Kenya (AMRO-Kenya) -- which was established and registered under the Society Act Cap 108 in February 1975 -- undertook and coordinated training, registration, and licensing functions until the Board formally took over all the functions the Association previously performed.

The Regulatory Impact Statement (RIS) process involves an assessment of regulatory proposals and allows members of the public to comment on proposed Rules and Regulations before they are finalized. Such public input provides valuable information and perspectives and improves their overall quality. Under the Statutory Instruments Act, Cap. 2A on regulation making, a regulation-making authority shall ensure that Rules and regulations are appropriate, effective and impose the lowest possible burden on Kenyan businesses and the community.

A RIS is usually prepared before a new government regulation is introduced to provide a detailed and systematic appraisal of the potential impact of a new regulation. It also helps assess whether the Rules and Regulations will achieve the desired objectives. The RIS promotes evidence-based policymaking as new Rules and Regulations typically lead to numerous impacts that are often difficult to foresee.

From a societal viewpoint, the RIS should confirm whether the proposed regulation is welfare-enhancing, in that, the benefits will surpass the costs. A Regulatory Impact Statement, therefore, aims at 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.

1.2 REGULATION-MAKING AUTHORITY AND THE LEGAL MANDATE

The HRIM board is a creation of the law mandated to provide general guidance over training, registration, and licensing of health records and information managers in Kenya, and to advise the Cabinet Secretary on matters related to professional practice.

Section 38 of the Health Records Managers Act, Cap. 539 empowers the Board, in consultation with the Cabinet Secretary, to make Rules for the better carrying out of the provisions of this Act, the Rules made may provide for;-

(a) the attendance of witnesses and the production of books and documents at an inquiry held by the Board;
(b) forms to be used in connection with this Act or fees to be charged under this Act;
(c) the conditions of admission to the registers and the issue of licenses;
(d) how the various categories of persons for whom provision is made in this Act for registration or enrolment may be established and their training regulated;
(e) the conditions under which training schools for persons desirous of obtaining registration under this Act may be approved and the courses of training and instruction to be undergone by persons seeking such registration or enrolment;
(f) the subject matter of training courses and examinations to be conducted by the Board;
(g) the conditions of admission for entry to training courses and examinations to be conducted by the Board;
(h) the standards and conditions of professional practice of persons registered, or licensed under this Act;
(i) the fees payable in respect of examinations, registration, issue of licenses, issue of certificates and badges, and in respect of any other matters under this Act;

(j) the procedure for election of the chairperson and the vice-chairperson;
(k) the powers and duties of local supervising authorities, and the distinct powers and duties that may be prescribed for different local supervising authorities;
(l) provide for the disposal of fees collected, the authorization of such disbursements as may be necessary, and the management of any funds within the control of the Board;
(m) the keeping and opening of new registers and records and the closing of existing registers, rolls, and records or parts thereof.

The authority of the Board and the Cabinet Secretary to make Rules and Regulations is limited to bringing into effect the provisions of the HRIM Act, Cap.539.

This RIS has been prepared to facilitate public consultation on the proposed Rules and Regulations. Its preparation adhered to the Statutory Instruments Act, Cap 2A requirements. The statutory instruments are intended to give full effect to the Health Records and Information Managers Act, Cap 539.

1.3 REQUIREMENTS OF THE STATUTORY INSTRUMENTS ACT, CAP 2A.

A Regulatory Impact Statement is a systematic policy tool used to examine and measure new or existing Rules and Regulations' benefits, costs, and effects. It is also an analytical report that assists decision-makers in making informed policy decisions. In this way, the RIS evaluates feasible alternative regulatory and non-regulatory approaches that ensure the final selected regulatory approach provides the greatest net public benefit.

Under sections 6 and 7 of the Statutory Instruments Act, Cap. 2A, if a proposed statutory instrument is likely to impose significant cost to a whole or part of the community, the regulation-making authority shall prepare a regulatory impact statement before making the statutory instrument.

Under the Statutory Instruments Act, a regulatory impact statement shall contain:

a) a statement of the objectives of the proposed statutory instrument and the reasons for them;

b) a statement explaining the effect of the proposed statutory instrument, including in the case of a proposed statutory instrument which is 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 alternative regulatory as well as non-regulatory options;

d) an assessment of the costs and benefits of the proposed statutory instrument 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 statutory instrument; and

g) a draft copy of the proposed statutory instrument.

Section 5 of the Statutory Instruments Act, Cap. 2A, further 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 an adequate opportunity to comment on its proposed content.

CHAPTER 2

BACKGROUND AND CONTEXT

2.1 INTRODUCTION

A Health Records and Information Management (HRIM) professional is defined in the Health Records and Information Managers Act No 15 of 2016, as **"a health records and information management professional trained from a HRIM Board-accredited institution, registered and licensed by the Board."** This is the discipline that deals with health and health-related data in all undertakings, and considering technological advancement, the use of emerging health technologies such as computers, tablets, phones, software and telecommunication, EMRs, telemedicine, and EHRs technologies.

The core functions of the professional include creating, maintaining, implementing, and managing health records and information services such as patient information systems, and clinical and administrative data, to meet the medical, legal, ethical, and administrative requirements of health care delivery, or who teaches or performs research in these areas.

The health information management professional works and applies their knowledge and skills to create, acquire, code and index diseases based on the ICD family of diseases, manage patients' appointment systems, and conduct analysis and management of health information to meet the clinical, legal, ethical and administrative requirements of the health care system per policies and guidelines set by the HRIM Board

Health records and information management professionals play a pivotal role in the health sector by providing information services needed to generate quality and timely data used to inform decision-making processes.

The profession is also mandated to undertake monitoring and evaluation functions for the various health programs and to perform a detailed analysis of program data in the health ecosystem to facilitate healthcare service delivery, guarantee patient safety, and support evidence-based decisions. It also plays a significant role in ensuring that a patient's privacy and confidentiality are achieved, while acting as an advocate of the patient's right

to privacy as they (the patient) interact with service providers. The HRIM cadre also supports the clinical coding of diseases and procedures that aid in data classification to support health research.

In their professional capacity, HRIM professionals provide health and health-related informatics services, thereby occupying a central and special position in the modern healthcare delivery system. It is appropriate that the professionals adhere to the expected conduct of practice and behavior while dealing with their core responsibilities.

Article 31 of the Constitution of Kenya provides and safeguards citizens' rights to privacy. Guided by the law, the ethical obligations of the HRIM professionals under this constitutional right include, but are not limited to, the safeguarding of privacy and security of all health records and health information; appropriate disclosure of health information; development, use, and maintenance of health information systems and health information; and ensuring the safety of the data from the data subjects, accessibility and integrity of health information.

With generational changes, advancement in technology, and the ever-increasing number of healthcare consumers aware of their rights and fundamental state responsibilities, concerns about security, loss of privacy, and the inability to control access and disclosure of their personal health information have occupied most discussions across the health sector. It has been observed that these core health information issues regarding collection, management, and access to protected health information, including access conditions, disclosure, retention, and disposal are becoming increasingly important to professionals.

This situation gives a compelling need for all core health information professionals to adhere to and comply with provisions of existing international laws and instruments, the Constitution of Kenya (COK) 2010, the Kenya Health Act 2017, the Health Records and Information Managers Act No 15 of 2016, the eHealth draft Bill 2022, Data Protection Act 2019, Professionals code of ethics for HRIM managers and any other relevant health policies and procedures both domestic and internationally.

2.2 HISTORY OF HEALTH RECORDS AND INFORMATION MANAGEMENT

Health records date back to ancient civilizations, with early examples in Egypt, Greece, and Rome. The Egyptians recorded medical treatments and diagnoses on papyrus scrolls, while Hippocrates in Greece emphasized detailed clinical observations. Monastic European communities kept records of diseases and treatments, contributing to the preservation and transmission of medical knowledge.

In the 1850s, Nightingale's work during the Crimean War highlighted the importance of accurate record-keeping in improving patient outcomes which led to the establishment of statistical societies in the UK and the US began to formalize health data collection and analysis.

In the early 1900s, the development of health information management (HIM) as a formal field began, with hospitals starting to maintain patient records systematically. The American Health Information Management Association (AHIMA) was founded in 1928, and the World Health Organization (WHO) was established in 1948, standardizing health records and data collection methods.

WHO and other international bodies promoted global standards for health records. The International Classification of Diseases (ICD) became a global standard for recording diseases and health conditions.

HRIM has been recognized in Kenya since the year 1975. In 1978, Kenya trained the first cohort of Certificate in Medical Records Officers from the Kenya Medical Training College (KMTC). Previously, health records and information management professionals used to be trained in the United Kingdom (UK).

In the 1980s and 90s, Kenya started to develop more structured health information systems (HIS) to improve data collection and reporting. This period saw the introduction of basic computer systems in some health facilities, as the Ministry of Health (MOH) implemented the District Health Information Software (DHIS) system to collect, analyze, and disseminate health data from different regions.

These efforts to implement electronic health records gained momentum, supported by international donors and non-governmental organizations.

Programs like the Kenya Health Information System (KHIS) aimed to digitize health records.

The Health Act of 2017 included provisions for establishing a comprehensive health information system, underscoring the importance of accurate and accessible health records. The profession has grown over time and from 2009 to date, more than eight universities and fourteen medical training college campuses offer training in this course at certificate, diploma, and degree levels. The TIVETA registered and licensed institutions are also offering courses in an environment of self-autonomy thus lacking the regulatory mandate enshrined in the HRIM Act 15 of 2016.

While considerable progress has been made, ongoing challenges need to be addressed to fully realize the potential of health information systems in improving healthcare outcomes. The HRIM Board has been working to strengthen and ensure that all HRIM training programs meet and equip students with core competencies and standards set by the Board.

CHAPTER 3

EVALUATION OF THE PROBLEM

3.1 INTRODUCTION

The enactment of the Health Records and Information Managers (HRIM) Act, Cap.539 in Kenya marked a significant step towards formalizing and regulating the HRIM field. The Act was intended to provide for the training, registration and licensing of health records and information managers and to regulate their practice.
However, several problems persist in the areas of training, practice, registration, and licensing of health records and information managers due to gaps in legislation and regulatory enforcement. Some of the key issues include:

a) **Implementation Delays and Inadequate Enforcement Mechanisms.** Despite the enactment of the HRIM Act, there have been delays in developing and implementing the necessary regulations to operationalize the Act fully. The Act lacks robust enforcement mechanisms, leading to

inconsistent adherence to standards and practices across different health facilities.

b) **Training and Education Challenges**. There is a need for standardized curricula across training institutions to ensure consistency and quality in the education of HRIM professionals. Variations in training programs can lead to disparities in skills and knowledge among graduates. Not all institutions offering HRIM courses are accredited, resulting in graduates with varying levels of competence. The process for accrediting these institutions needs to be streamlined and enforced. The framework for CPD is often underdeveloped or poorly enforced, which limits opportunities for HRIM professionals to update their skills and knowledge.

c) **Registration and Licensing Issues.** The processes for registering and licensing HRIM professionals can be cumbersome and bureaucratic. The capacity of the Board to manage registration and licensing efficiently is sometimes inadequate due to issues such as understaffing, lack of proper infrastructure, and the lack of procedures for the recognition of qualifications from different institutions, especially those obtained abroad. The Act will facilitate and enforce the registration and licensing of HRIM professionals practicing in Kenya while guiding the collection of fees to maintain the Board's operations.

d) **Practice Standards and Compliance.** There is a need for more uniform and comprehensive practice standards across the country. Currently, there can be significant differences in how HRIM practices are carried out in different regions and facilities. Effective monitoring and evaluation mechanisms are often lacking, making it difficult to ensure compliance with established standards and rules/regulations.

e) **Data Privacy and Security.** With the digitization of health records, ensuring data privacy and security has become a major challenge. Legislation and statutory instruments must be more robust in addressing these issues to protect patient information. There are still gaps in the legal framework concerning the responsibilities and liabilities of HRIM professionals, which can lead to ambiguities in practice.

f) **Stakeholder Engagement and Awareness.** There is often low awareness among stakeholders, including health professionals and the public, about the importance of HRIM and the rules and regulations governing it. This can lead to a lack of compliance and support for regulatory measures. Effective implementation of the HRIM Act requires active involvement and cooperation of various stakeholders, including training institutions, healthcare providers, and regulatory bodies. Coordination among these entities is sometimes insufficient.

g) **Funding and Resources.** Adequate funding is crucial for developing and maintaining high-quality HRIM systems and training programs. Insufficient financial resources can hinder the implementation of

regulatory measures and the improvement of HRIM practices. There can be misallocation or inefficient use of resources, which affects the capacity to enforce rules and regulations and support HRIM professionals adequately.

3.2 CONCLUSION

These Rules and Regulations will streamline the registration and licensing processes to make them more efficient and transparent; enhance the capacity of the regulatory body overseeing HRIM; develop and enforce uniform practice standards and robust monitoring and evaluation mechanisms; strengthen legal frameworks to address data privacy, security, and professional liability issues; strengthen the legal and institutional framework needed to secure adequate funding and ensure efficient resource allocation to support HRIM infrastructure and initiatives.

To address these issues, the following recommendations can be made to accelerate the development and implementation of comprehensive Rules and Regulations to operationalize the HRIM Act effectively and ensure standardization of the HRIM profession while enforcing accreditation and curriculum requirements for HRIM training programs. By addressing these challenges, Kenya can improve the regulation and practice of health records and information management, enhancing the quality of healthcare services in the country.

CHAPTER 4

POLICY AND LEGAL FRAMEWORK FOR THE RULES AND REGULATIONS

4.1 INTRODUCTION

The regulation of health records and information management in Kenya is governed by a comprehensive policy and legal framework designed to ensure the privacy, security, and accuracy of health information.

4.2 CONSTITUTIONAL MANDATE

The Constitution of Kenya (COK) 2010 guarantees certain basic rights and fundamental duties that guide HRIM professional practice and behaviours. Article 43 (1)(a) of the Constitution of Kenya guarantees the highest attainable standard of health, which includes the right to health care services, including reproductive health care.

Article 43 (1)(a) of the Constitution of Kenya guarantees the highest attainable standard of health, which includes the right to health care services, including reproductive health care. The Constitution provides a broad framework for the right to privacy and access to information. For instance, Article 31, guarantees the right to privacy, including that of personal information, while Article 35 provides for the right of access to information held by the state and any information held by another person and required for the exercise or protection of any right or fundamental freedom.

The Constitution requires 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. The Fourth Schedule recognizes health services as a devolved function whereas training, policy, and standards are a national government function.

4.3 HEALTH RECORDS AND INFORMATION MANAGERS ACT.

The Health Records and Information Managers Act, Cap. 359 was enacted to regulate the training, registration, and licensing of health records and information managers in Kenya.

The Act establishes the Health Records and Information Managers Board, defines its functions, and sets out the requirements for the practice of health records and information management. The Board's functions include regulating the training and practice of health records and information management, maintaining a register of practitioners, and ensuring the standards and quality of health records management.

After registration, individuals must obtain a practicing license, which is subject to renewal. The Board has the authority to issue, renew, suspend, or revoke licenses based on compliance with the Act's provisions.

The Board establishes a code of conduct for health records and information managers, ensuring ethical practice and professionalism. It can investigate complaints against practitioners and take disciplinary actions, including suspension or revocation of licenses for misconduct or incompetence.

To ensure standardization and quality of training of HRIM professionals the Board accredits institutions that offer training in health records and information management and ensures that the curriculum and training standards meet the requirements for professional practice.
The Act defines the scope of practice for health records and information managers, including the management of health records, data protection, and ensuring the confidentiality of patient information. Practitioners are encouraged to engage in continuous professional development to maintain their competency and stay updated with advancements in the field.

Practicing without registration and a valid license is an offense punishable by fines and/or imprisonment and breaches of patient confidentiality and misuse of health records are subject to penalties.

In summary, the Act aims to ensure that professionals in this field are professionally trained, registered, and licensed and that they adhere to high standards of practice and ethics which are critical for maintaining the

integrity, confidentiality, and security of health information in Kenya's healthcare system.

4.4 LEGAL FRAMEWORK GOVERNING HEALTH RECORDS

1. HEALTH ACT, CAP.241

The Health Act is a primary legislation that governs health services in Kenya. Section 5 of the Health Act states that every person has the right to the highest attainable standard of health which also includes progressive access to the provision of promotive, preventive, curative, palliative, and rehabilitative services.

The Health Act, under Sections 104 (b), (c), and (d) directs the Ministry of Health to develop guidance on the collection and use of personal health information, management of its disclosure, and protection of patient privacy. The role of the HRIM, provided for under Section 73, mandates the creation and maintenance of health records for every patient by health service providers. Section 74 stipulates that health records should be kept confidential and only disclosed under specific circumstances, such as for treatment, with the patient's consent, or by law.

2. DATA PROTECTION ACT, CAP. 411C

The Kenya Data Protection Act, defines health data as "any information concerning the physical or mental health of an individual, including information regarding the provision of healthcare services to the individual." This includes but is not limited to medical records, diagnoses, treatment plans, prescription information, and laboratory results.

The DPA, 2019 recognizes the sensitive nature of health data and provides additional safeguards and restrictions on its collection, use, and disclosure to protect individuals' privacy and confidentiality.

Sections 25, 31, and 46 of the Act regulate the collection, processing, storage, and retention of sensitive personal data. It provides a comprehensive framework for data protection in Kenya, applicable to all sectors, including health. The Act establishes the rights of data subjects, including the right to be informed, the right to access, the right to rectification, and the right to erasure. It outlines the obligations of data controllers and processors;(to which the HRIM professionals belong); including obtaining consent, ensuring data security, and reporting data breaches.

These Rules and Regulations protect the privacy of data subjects in line with the Constitution. The Act also defines the principles and obligations of personal data protection.

3. THE DIGITAL HEALTH ACT NO.15 OF 2023

The Digital Health Act provides a framework for providing digital health services and establishes a comprehensive integrated digital health information, communication, and technology system. This system will provide data governance and protection of personal health information and service delivery through digital health interventions such as telemedicine, e-waste disposal, and health tourism. The Act establishes the Digital Health Agency which is mandated to regulate the provision of digital health services in Kenya.

The Comprehensive Integrated Health Information System established under the Act manages the core digital systems and the infrastructure required for seamless health information exchange. Having an integrated system addresses the challenges posed by fragmented and siloed health data systems. Further, by centralizing health information in a secure and standardized manner, healthcare providers can access comprehensive patient data leading to more informed diagnoses and treatment decisions[1].
The system is intended to facilitate a people-centered quality health service delivery, to facilitate data collection and reporting at all levels of health care provision, to enable secure health data sharing for timely and informed inter-facility health service delivery, to facilitate data processing and use for informed decision- making at all levels, to safeguard the privacy, confidentiality, and security of health data for information sharing and use, and to facilitate the tracking and tracing of health products and technologies in the country, among others.

4. PUBLIC HEALTH ACT, CAP 242

The Public Health Act includes provisions related to the management of health information in the context of public health; Section 15 provides for the collection and use of health information for the control of communicable diseases, while Section 35 empowers health authorities to collect information necessary for the prevention of public health risks.

[1] Digital Health Act, 2023

5. ACCESS TO INFORMATION ACT, CAP 7M.

This Act gives effect to the right of access to information by citizens as provided under Article 35 of the Constitution and provides a framework for public entities and private bodies to proactively disclose information and to provide information on request in line with the constitutional principles.

The Act also guides access to information requests. While the DPA (Section 38 (1)) provides for the right for a data subject to receive personal data concerning them in a structured and machine-readable format, the Access to Information Act provides a guideline on "how to provide access by each person to official information relating to that person."

6. PUBLIC ARCHIVES, RECORDS AND DOCUMENTATION SERVICE ACT,CAP. 19

This is an Act of Parliament that provides for the preservation of public archives and records for connected purposes.

7. PUBLIC HEALTH ACT,CAP. 241

This Act speaks to the protection of public health in Kenya. However, it does not provide any specific relevant guidance on the governance of public health data.

8. KENYA INFORMATION AND COMMUNICATIONS ACT, CAP.411A

The main aim of this Act is to regulate electronic data as legal data. It enforces the retention of electronic records and information in its original form.

Section 83 G: Defines electronic records as legal records.

Section 83 H: Provides for period retention of electronic records.

Section 83 I: Requires retention of information in its original form.

These have been some of the guiding principles in the development of HRIM Rules and Regulations.

8. THE KENYA HEALTH POLICY, 2014-2030

The Kenya Health Policy, 2014-2030 is oriented towards promoting the use of health information systems to improve health outcomes and health system performance. The policy recognizes the critical role of reliable and timely health information in effective decision-making, planning, and management of the health system at all levels. The policy also emphasizes the importance of interoperability and integration of health information systems across

distinct levels of the health system to ensure the seamless sharing of health information.

The health policy prioritizes the use of technology to enhance data quality and reduce data management costs. It also emphasizes the need to build capacity in health information management and promote stakeholder engagement and ownership of health information systems deployed to support healthcare delivery.

These Rules and Regulations acknowledge the importance of protecting the privacy and confidentiality of health information through appropriate security and privacy measures. Overall, they aim to create a robust, efficient, and responsive health information system that supports evidence-based decision-making and contributes to better health outcomes for all Kenyans.

9. THE KENYA HEALTH DATA GOVERNANCE FRAMEWORK (KHDGF) 2023- 2028

The Framework was developed against the backdrop of optimal digitization within the health ecosystem as a critical pillar to attaining Universal Health Coverage. It is responsive to the fact that technology has immense benefits on the one hand, but, on the other hand, introduces potential risks and exposures. This framework provides structure and guidance for managing health data to optimize the inherent value of data, and to foster science, technology, and innovation in managing the health ecosystem while ensuring utmost adherence to the protection of health data. It envisions a healthcare system that effectively, ethically, equitably, and lawfully manages health data.

The global health data governance principles form a foundational framework that guides the responsible and ethical management of health-related information. These principles encompass privacy protection, transparency, and equitable utilization to ensure the integrity and reliability of health data. The principles have been referenced and contextualized in these Rules and Regulations to ensure alignment with international practice whilst acknowledging our uniqueness as a country.

The organizational governance structures described in the Framework, including the Digital Health Agency and the roles of both the National and County Governments, are designed to ensure stakeholders are coordinated to implement data protection provisions in the Framework while promoting and encouraging activities that amplify and maximize the health value of data through innovation, ethical data sharing, and ethical data use for patient care and public health.

It encourages the ethical use of data for innovations, such as Artificial Intelligence and Machine Learning, that target and facilitate access to the highest attainable standard of health for the most vulnerable populations, accelerating the attainment of Universal Health Coverage. The Kenya Health Data Governance Framework guides the management of data security risks, particularly the unauthorized access to and use of sensitive health information. Additionally, and referring to the Data Protection Act, 2019 and Digital Health Act, 2023, this Framework outlines the procedures that regulate and ensure ethical and responsible oversight of data throughout the entire data value chain that includes data collection, data access and sharing, data anonymization, pseudonymization and de-identification, data analysis and visualization, data usability, data retention, and data disposal.

10. HEALTH SECTOR UNIQUE IDENTIFICATION FRAMEWORK, AUGUST 2022

The health sector's unique identification framework is multifaceted and aims to facilitate the achievement of benefits across various levels of healthcare provision by uniquely identifying citizens and tracking holistic, historical information to provide quality, focused healthcare. The levels of healthcare covered in this Framework include the patient level, service delivery level, and public health level, as described below:

- **Patient Level**: Unique Patient Identifier (UPI) improves patient management and quality of care by enabling accurate identification and the sharing of health records which inform clinical decision-making across the continuum of care. This improves patient safety by reducing the risk of medical errors, such as wrongful administration of medication or surgery on the wrong patient, while strengthening longitudinal patient care irrespective of service points.
- **Service Delivery Level**: UPI promotes efficiency in healthcare delivery by enabling efficiencies in the direct delivery of health services. This includes enhancing administrative tasks, clinical services and referrals through real-time identification of clients relative to the services they need. In doing so, it also supports optimization of resource utilization, for example, avoiding unnecessary or repeated procedures and diagnostic tests.
- **Public Health Level**: UPI facilitates disease surveillance (during disease outbreaks, for instance), promotes data quality by eliminating double counting of cases, and supports research and targeted interventions and resource allocation. Within the confines of health

data governance, the establishment of the UPI is a major step toward patient-centered care, facilitating portability of personal data, ensuring health data ownership is domiciled in a legal person and enabling the effective exchange of health information for patient care. The health data governance Framework further reinforces the relevant provisions of the UPI policy to ensure maximum achievement of UPI benefits while protecting patients and clients from harm.

11. KENYA HEALTH SECTOR STRATEGIC AND INVESTMENT PLAN (KHSSP) 2018-2023

This strategic plan outlines the policies and strategies for health information management. It emphasizes strengthening health information systems (HIS) to ensure timely, accurate, and reliable health data, and promotes the use of electronic health records (EHRs) and interoperability between health information systems.

12. NATIONAL HEALTH INFORMATION SYSTEM POLICY, 2010

This policy guides the development and implementation of health information systems in Kenya. The policy aims to ensure the availability of high-quality health data for decision-making. It supports the integration and harmonization of various health information systems.

13. KENYA NATIONAL EHEALTH POLICY 2016-2030

The eHealth policy provides a framework for adopting digital health technologies and promotes the implementation of EHRs and other health information technologies. It addresses issues related to data security, privacy, and interoperability.

14. KENYA HEALTH SECTOR DATA QUALITY ASSURANCE (DQA) PROTOCOL

The DQA protocol provides a framework and uniform approach to which all stakeholders and partners can refer when implementing activities towards quality assurance of health data across the value chain. This protocol lays out processes and procedures designed to achieve the following objectives:

- Assessing the quality of health data through internal and external routine audits and supportive supervision,
- Using data quality assessment findings to identify and implement solutions,

- Implementing data quality improvement strategies.

15. STANDARDS AND GUIDELINES FOR ELECTRONIC MEDICAL RECORDS SYSTEMS IN KENYA

This policy document was developed to guide implementers of EMR systems in Kenya. It includes the following aspects of EMR data that are relevant to the governance of patient-level data:

- The essential minimum data using the National HIV program as a reference health use case.
- The minimum functional capabilities that every electronic patient management information system such as an EMR system needs to provide to ensure the collection, processing and use of patient-level data.
- The data and interoperability standards that every electronic patient management information system such as an EMR system should implement and ensure continuous conformance.

A successor to these Standards and Guidelines for Primary Healthcare, Electronic Medical Records Systems in Kenya is the Digital Health regulations that have been developed to address the current needs that electronic health records require to support primary healthcare. The HRIM Rules and Regulations will support the full implementation of these legislations.

4.5 IMPLEMENTATION AND OVERSIGHT OF THE LEGAL AND POLICY FRAMEWORKS.

The legal and policy frameworks stipulated in this chapter focus on the implementation and operationalization of national laws at the county level. The Ministry of Health (MoH) is responsible for policy formulation, oversight, and coordination of health services, including health information management. The Office of the Data Protection Commissioner oversees compliance with the Data Protection Act, including in the health sector while regulatory bodies -- the HRIM Board in this context -- regulate Health Records and Information professionals and ensure adherence to standards related to health records management.

These legal and policy frameworks collectively aim to safeguard patient privacy, ensure data accuracy, and promote the efficient use of health information for better healthcare outcomes in Kenya.

CHAPTER 5

OBJECTIVE OF THE HEALTH RECORDS AND INFORMATION MANAGERS RULES AND REGULATIONS 2025

5.1 OBJECTIVES OF THE RULES AND REGULATIONS

The objective of the Health Records and Information Rules Regulations, 2025 is to give full effect to the Act. Specifically, the Regulations aim to give guidance to: -

a) Registration of health records information managers,
b) Licensing of health records and information managers,
c) Accreditation of training institutions,
d) Harmonization of health records information and management training,
e) Provide standards and ensure quality and relevance in HRIM training,
f) Provide a procedure for discipline, termination, suspensions, and revocation of HRIM license.

The Rules also prescribe fees, forms and other matters required to be factored under the Act.

5.2 SPECIFIC OBJECTIVES OF THE RULES AND REGULATIONS

The Specific objectives of the rules and regulations provide a structured regulatory framework for training, registration, licensing, examination, fees, and disciplinary processes within the Health Records and Information Management profession.

Table 1:Specific Objectives of the Rules and Regulations

	Regulation/ Rule	Objective
1)	Health Records and Information Managers (Approval and Accreditation of Training Institutions) Regulations, 2025	The objectives of the Regulations are to: (a) Establish a framework for the approval and accreditation of training institutions offering health records and information management programs. (b) Define the procedures for applying for approval, inspection, and issuance of certificates to training institutions. (c) Set academic requirements, including curriculum standards, admission criteria, and quality assurance mechanisms. (d) Regulate the termination, suspension, and revocation of approval for training institutions. (e) Ensure compliance with the Data Protection Act regarding personal data handling in training institutions.
	Rule	**Objective**
2)	Health Records and Information Managers (Fees) Rules, 2025	The objectives of the Rules are to: (a) Specify the fees payable for various services under the Health Records and Information Managers Act. (b) Regulate the charges for registration, licensing, indexing of students, and examinations. (c) Establish the financial obligations of training institutions seeking accreditation and approval. (d) Outline penalties for non-compliance with fee payment rules. (e) Provide a structured fee schedule for various levels of academic qualification and services.
	Rules	**Objective**
3)	Health Records and Information Managers (Registration and Licensing) Rules, 2025	The objectives of these Rules are to: (a) Provide a structured process for registering health records and information managers. (b) Establish criteria for obtaining a license to practice as a health records and information manager. (c) Regulate the maintenance of the register of managers, including updates, corrections, and removal procedures.

		(d) Define licensing conditions, including compliance with professional development requirements. (e) Ensure adherence to data protection and digital health regulations in the registration and licensing process.
	Rules	**Objective**
4)	Health Records and Information Managers (Examinations) Rules, 2025	The specific objectives of these Rules are to: (a) Define the examination requirements for the registration of health records and information managers. (b) Establish standards for the administration, conduct, and processing of examination results. (c) Set rules for handling examination irregularities, including cancellation and withholding of results. (d) Provide examination accommodations for candidates with disabilities. (e) Regulate the process of appeal, remarking, and supplementary examinations
	Rules	**Objective**
5)	Health Records and Information Managers (Inquiry and Disciplinary Proceedings) Rules, 2025	The objectives of the Rules are to: (a) Establish procedures for handling complaints and disciplinary inquiries against health records and information managers. (b) Define the steps for submitting, reviewing, and determining the merit of complaints. (c) Outline the hearing procedures, including the rights of the accused and the role of the disciplinary committee. (d) Set rules for decisions, appeals, and restoration in the register following disciplinary action. (e) Uphold professional standards and ethical practices among health records and information managers.

CHAPTER 6

AN OVERVIEW OF THE RULES AND REGULATIONS

1. *Health Records and Information Managers (Approval and Accreditation of Training Institutions) Regulations, 2025*

The regulations on Approval and Accreditation of Training Institutions provide a regulatory framework for approving and accrediting institutions that offer training in health records and information management.

They outline the procedure for applying for approval as a training institution in Health Records and Information Management, including submission requirements and inspections.

They set academic standards, covering curriculum, admission requirements, and quality assurance. Additionally, they specifies conditions under which accreditation may be suspended, revoked, or terminated. The document also includes provisions for compliance with data protection laws to ensure the security of student records.

2. *Health Records and Information Managers (Registration and Licensing) Rules, 2025*

Health Records and Information Managers (Registration and Licensing) Rules 2025 establish the requirements and process for registering and licensing health records and information managers.

They detail the application process, including required documentation and eligibility criteria for individuals trained locally and internationally. They also govern the maintenance of the register of managers, including updates, corrections, and removal of names.

The Rules specify licensing conditions, renewal procedures, and standards of practice to ensure compliance with professional and ethical requirements. Additionally, they provide requirements for continuing professional development and the procedure of registration of institutions that offer continuing professional development courses.

3. *Health Records and Information Managers (Examinations) Rules, 2025*

These Rules regulate the administration of examinations required for registration as a health records and information manager.

They define the structure of the exams, which include written, practical, and oral components. They outlines application procedures, examination subjects, withdrawal policies, and the process for handling candidates with disabilities.

The Rules also cover the grading system, release of results, remarking, supplementary exams, and disciplinary measures for examination irregularities.

4. *Health Records and Information Managers (Inquiry and Disciplinary Proceedings) Rules, 2025*

The Rules on Inquiry and Disciplinary Proceedings set out the procedures for handling complaints and disciplinary inquiries against registered health records and information managers.

They detail how complaints can be submitted, reviewed, and investigated. The Rules outline the hearing process, including the rights of the accused, evidence presentation, and decision-making by the disciplinary committee. They provide applicable penalties which include suspension, removal from the register, and restoration procedures.

5. *Health Records and Information Managers (Fees) Rules, 2025*

These Rules define the fees payable for various activities under the Health Records and Information Managers Act.

They provide charges for registration, licensing, student indexing, examinations, and approval of training institutions. It also outlines penalties for past due payments and non-compliance.

CHAPTER 7

THE COST-BENEFIT ANALYSIS

7. 1 INTRODUCTION

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

The implementation of Health Records and Information Managers Rules and Regulations in Kenya, facilitated by the Digital Health Act of 2023 and the Data Protection Act of 2019, presents significant opportunities for improving healthcare delivery. While the initial costs and challenges are considerable, the long-term benefits in terms of improved patient care, operational efficiency, and data-driven decision-making make it a worthwhile investment. Ensuring robust data security measures and compliance with legal requirements will be crucial to realizing these benefits fully.

7.2 BENEFITS AND COSTS OF THE PROPOSED RULES AND RULES AND REGULATIONS

The analysis of the expected costs and benefits of the proposed rules and regulations contained in this part seeks to answer the question of whether the benefits justify the costs. This enables the Regulator to estimate the total expected cost and benefit of every aspect of the Regulations.

The objective of the proposed Rules and Regulations is to provide a framework for improved outcomes and financial protection in line with the right to health and universal health coverage.

Implementing these Rules and Regulations involves various costs related to administration, compliance, and enforcement. However, the benefits, including improved professional standards, public trust, accountability, and the overall quality of health records management, significantly outweigh the costs.

7.3 MATRIX OF BENEFITS AND COSTS ON THE RULES AND REGULATIONS

Table 3: Summary of Costs and Benefit Analysis per Regulation

Regulation	Cost	Benefit
Health Records and Information Managers (Registration and Licensing) Rules, 2025	▪ **Administrative Costs:** Establishing and maintaining a registration and licensing system involves administrative expenses, including staff salaries, office infrastructure, and IT systems. ▪ **Compliance Costs for Practitioners:** Health records and information managers may incur costs for registration fees, licensing fees, and costs related to fulfilling continuing education requirements. ▪ **Enforcement Costs:** Monitoring compliance and taking enforcement actions against unlicensed practitioners involve additional costs.	▪ **Professional Standards:** Ensures that only qualified individuals practice, thereby enhancing the quality of health records management. ▪ **Public Trust:** Builds public trust in the healthcare system by ensuring that licensed professionals manage health records. ▪ **Accountability:** Creates a mechanism for accountability and recourse in cases of malpractice or misconduct.
Health Records and Information Managers	▪ **Accreditation Process:** Costs	▪ **Quality Education:** Ensures that

(Approval and Accreditation of Training Institutions) Regulations, 2025	associated with the evaluation and accreditation of training institutions and programs, including site visits and assessment procedures. ▪ **Institutional Costs:** Training institutions may incur costs to upgrade facilities, hire qualified faculty, and align their courses with accreditation standards.	training programs meet specified standards, leading to well-prepared health records and information managers. ▪ **Consistency:** Promotes uniformity in the education and training received by all health records professionals. ▪ **Employer Confidence:** Increases employer confidence in the qualifications of graduates from accredited programs
Health Records and Information Managers (Inquiry and Disciplinary Proceedings) Rules, 2025	▪ **Inquiry and Investigation Costs:** Resources are required to conduct inquiries and investigations into complaints, including personnel, legal, and administrative costs. ▪ **Legal Costs:** Expenses related to legal proceedings and potential settlements or penalties	▪ **Maintaining Standards:** Upholds professional standards and ethics by addressing misconduct and incompetence. ▪ **Protecting Public Interest:** Protects the public from harm due to professional malpractice or ethical breaches. ▪ **Deterrence:** Acts as a deterrent against unprofessional behavior and promotes adherence to the code of conduct.

Health Records and Information Managers (Examinations) Rules, 2025	▪ **Development Costs:** Expenses related to developing and updating curriculum content and examination rules, including consultations with experts and stakeholders. ▪ **Training Costs:** Costs for training educators to deliver the updated curriculum and conduct examinations as per the new standards.	▪ **Relevant Curriculum:** Ensures that the curriculum is up-to-date and relevant to current industry standards and technological advancements. ▪ **Standardized Exams:** Creates a standardized examination process that ensures fairness and consistency in evaluating students' knowledge and skills. ▪ **Enhanced Competence:** Graduates are better equipped with the knowledge and skills required to manage health records effectively and efficiently.

CHAPTER 8

CONSIDERATION OF ALTERNATIVES TO THE RULES AND REGULATIONS

8. 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. Rules, Regulations or legislation should be the last resort in realizing policy objectives. The options considered under this Chapter are maintenance of the status quo, administrative measures and implementation the Rules and Regulations.

8.2 THE ALTERNATIVES

8.2.1 OPTION ONE: THE STATUS QUO

Maintaining the status quo means that no Rules and Regulations will be developed and therefore the Health Records and Information Managers Act, Cap 539 will not effectively be implemented. The development of the Rules and Regulations is a requirement of the Act which seeks to ensure adherence to provisions address the Act. As enacted, the Act requires these Rules and Regulations for its full implementation.

The failure to implement the specified regulations would have significant adverse effects on the health records and information management sector in Kenya. Some of the challenges include:

a) Without mandatory registration and licensing, there would be no formal mechanism to ensure that practitioners meet minimum competency and ethical standards. Unqualified or underqualified individuals might practice, leading to errors in health records management, potentially compromising patient care.
b) The absence of a regulated profession can erode public trust in the healthcare system, as patients may doubt the reliability and confidentiality of their health records.

c) There is no formal recourse for addressing misconduct or incompetence among health records managers.
d) Without accreditation, educational programs might not meet industry standards, producing graduates who are ill-prepared for the demands of the profession.
e) The absence of disciplinary regulations can lead to unchecked unethical behaviour and professional misconduct, undermining the integrity of health records management, and
f) The lack of standardized examination rules can lead to discrepancies in how students are evaluated, resulting in inconsistent competency levels among graduates.

Overall, not implementing these Rules and Regulations would lead to decreased quality of healthcare; data security risks, professional inefficiencies, and public health risks as inaccurate or poorly maintained health records can impede public health.

Implementation of these Rules and Regulations is crucial for ensuring high standards, accountability, and consistency in the health records and information management sector in Kenya. Without them, the quality of healthcare services and the integrity of health records management would be significantly compromised.

8.2.2 OPTION TWO: APPLICATION OF ADMINISTRATIVE MEASURES

This is a non-regulatory measure which, if applied, will depend on the good will of public officers to implement the provisions of the Act. Administrative measures involve issuance of directives and circulars to the various departments hoping that they will be implemented. Administrative measures do not have the force of law and may be challenged in courts of law.

The Rules and Regulations provide for the collection of fees to support the Boards activities and enforce adherence to standards and code of ethics, which non-adherence can result in penalty and/or imprisonment, these provisions should be provided for by law.

Furthermore, under the Data Protection Act, health data is classified as "sensitive personal data", and these regulations outline specific provisions for the handling, processing, and protection of such data reflecting its

sensitivity and the need to protect individuals' privacy. Compliance with these Rules and Regulations ensures that health data is processed lawfully, fairly, and securely, thereby safeguarding the rights and interests of data subjects.

8.2.3 OPTION THREE: IMPLEMENTATION OF THE RULES AND REGULATIONS

The adoption of the Rules and Regulations shall ensure the full implementation of the Health Records and Information Managers Act Cap 539. Implementing the following regulations offers numerous benefits for the health records and information management sector in Kenya.

1. Health Records and Information Managers (Registration and Licensing) Rules, 2025

Benefits:

- **Professional Standards:** Establishes and maintains high standards for health records management, ensuring that only qualified individuals are licensed to practice.
- **Quality Assurance:** Ensures that health records and information managers possess the necessary skills and knowledge, leading to improved accuracy and reliability in health records management.
- **Public Trust:** Enhances public confidence in the healthcare system by ensuring that competent and licensed professionals manage health records.
- **Accountability:** Provides a framework for holding practitioners accountable for their actions, thereby reducing malpractice and improving overall service quality.
- **Regulatory Compliance:** Ensures compliance with national and international standards and regulations related to health records management.

2. Health Records and Information Managers (Approval and Accreditation of Training Institutions) Regulations, 2025

Benefits:

- **Educational Quality:** Guarantees that training programs meet specific standards of excellence, leading to well-prepared graduates who can effectively manage health records.

- **Consistency:** Promotes uniformity in the education and training of health records managers, ensuring consistent knowledge and skills across the profession.
- **Institutional Improvement:** Encourages educational institutions to continually improve their programs to meet accreditation standards, fostering a culture of continuous improvement.
- **Employer Confidence:** Assures employers that graduates of accredited programs are competent and have received high-quality training.
- **Global Recognition:** Aligns training programs with international standards to enhance Kenyan health records professionals' global mobility and recognition.

3. Health Records and Information Managers (Inquiry and Disciplinary Proceedings) Rules, 2025

Benefits:

- **Professional Integrity:** Upholds the profession's integrity by addressing and deterring unethical behavior and professional misconduct.
- **Public Protection:** Protects the public from incompetent or unethical practitioners, thereby enhancing the safety and reliability of health records management.
- **Fairness and Justice:** Provides a fair and transparent process for investigating and resolving complaints, ensuring that disciplinary actions are justified and appropriate.
- **Continuous Improvement:** Identifies areas for improvement in practice and behavior, leading to the overall enhancement of professional standards.
- **Deterrence:** Acts as a deterrent against professional misconduct, promoting adherence to ethical standards and best practices.

4. Health Records and Information Managers (Examinations) Rules, 2025

Benefits:

- **Relevant Education:** Ensures that the curriculum remains relevant and up-to-date with current industry standards, technological advancements, and best practices.
- **Standardized Evaluation:** Establishes standardized rules for exams, ensuring fairness and consistency in the assessment of students' knowledge and skills.

- **Competent Graduates:** Produces graduates who are well-equipped to meet the demands of the profession, thereby enhancing the quality of health records management.
- **Alignment with Industry Needs:** Aligns educational content with the needs of the healthcare industry, ensuring that graduates can effectively contribute to the healthcare system.
- **Continuous Curriculum Development:** Promotes ongoing review and development of course content, ensuring that training programs evolve with advancements in the field.

Overall, implementing the Rules leads to:

- **Improved Healthcare Quality:** High standards in health records management contribute to better patient care and outcomes by ensuring accurate and reliable health information.
- **Enhanced Data Security:** Professionally trained and licensed professionals are better equipped to protect sensitive health data, ensuring confidentiality and compliance with data protection laws.
- **Professional Recognition:** Establishing a regulated profession enhances recognition and respect for health records and information managers, promoting professional pride and commitment.
- **Economic Benefits:** High-quality training and professional standards attract investment in the healthcare sector, potentially leading to job creation and economic growth.
- **Public Health Advancements:** Reliable health records are crucial for public health monitoring, research, and policy-making, contributing to improved public health strategies and outcomes.

Implementation of these Regulations will provide a comprehensive framework that enhances the quality, accountability, and professionalism of health records and information management in Kenya, benefiting the entire healthcare system and the public it serves.

8.3 CONCLUSION: THE PREFERRED OPTION

Based on the analysis, the third option (Implementation of the Rules and Regulations) is the preferred option. The other two options have little or no impact in addressing the problem.

8.4 IMPACT ANALYSIS OF THE OPTIONS

An impact analysis of the options justifies the purpose of formulating the Regulations and the challenges that the Rules and Regulations will address. It further justifies the selection of option three on formulating the Regulations by evaluating the socio-economic, environmental, and legal impact of the Regulations as shown in table 4 below.

Table 4: Impact Analysis of the Three Options

SR. No.	**IMPACT ON SECTORS**	**OPTION ONE:** **Maintaining the Status quo**	**OPTION TWO:** **Administrative measures**	**OPTION THREE:** **Implementation of the Rules Regulations**
1	Impact on Public Sector	Minimal Public trust in HRIM professionals.	Uncertain	Increase in public trust in HRIM professionals.
2	Impact on the Private Sector	Uncertainty on the quality, standard, and professionalism of HRIM.	Uncertain	Ensure engagement of professionals in HRIM even on private engagements.
3	Economic Impact	Uncertain	Uncertain	**Efficiency and Cost Savings:** • **Operational Efficiency:** Streamlined and accurate health records management reduces administrative burdens and operational inefficiencies in healthcare facilities.

				• **Reduced Costs:** Decreases the costs associated with medical errors, redundant tests, and delayed treatments by improving the quality of health records management. **Attraction of Investments:** • **Health Sector Growth:** High standards in health records management can attract investment into the healthcare sector, fostering growth and innovation. • **Economic Opportunities:** Creates job opportunities and stimulates economic activities related to health records management, training, and regulatory compliance. **Global Competitiveness:**

				• **International Standards:** Aligning with international standards enhances the global competitiveness of Kenya's healthcare system, potentially attracting international partnerships and collaborations. **Improved Health Outcomes:** • **Productivity Gains:** Better health outcomes lead to a healthier workforce, which can improve productivity and economic performance at a national level. • **Reduced Healthcare Costs:** Improved health records management can lead to better disease management and prevention, reducing long-

				term healthcare costs. **Educational and Institutional Development:** • **Enhanced Training Programs:** Accreditation and standardization of training programs improve the quality of education, producing a skilled workforce that meets industry needs. • **Institutional Growth:** Encourages institutions to continuously improve their programs to meet accreditation standards, promoting a culture of excellence and innovation.
4	Social Impact	No Impact	• Uncertain	**Improved Quality of Healthcare:** • **Accurate Health Records:** Ensures that health records

				are accurately maintained, leading to better diagnosis and treatment plans, and improving overall patient outcomes. • **Patient Safety:** Reduces medical errors and enhances patient safety by ensuring qualified professionals manage health records. **Increased Public Trust:** • **Professional Standards:** Establishes trust in the healthcare system by ensuring that certified and licensed professionals manage health records. • **Transparency and Accountability:** The regulations provide mechanisms for transparency and accountability, enhancing public

				confidence in health institutions. **Better Public Health Monitoring:** • **Data Reliability:** Reliable health records support effective public health monitoring, research, and policymaking, leading to better management of public health issues like disease outbreaks. **Enhanced Confidentiality and Privacy:** • **Data Protection:** Strengthens the protection of sensitive health data, ensuring patient confidentiality and compliance with data protection laws. • **Professional Development and Ethics:** • **Continuous Learning:** Encourages continuous professional

				development and adherence to ethical standards, fostering a culture of lifelong learning and professional integrity.
5	Human Rights Impact		• Uncertain	Assurance of Privacy on Health-related Data
6	Impact on business	No impact	No Impact	No impact
7	Impact on environment	No Impact	No Impact	No impact
8	Impact on taxes	No Impact	No Impact	No impact
9	Impact on existing legal frameworks	• The existing legal gaps will not be addressed.	• Regulatory concerns will remain un-addressed	• Addresses all the identified gaps. • Provides harmony with related legal frameworks

CHAPTER 9

PUBLIC PARTICIPATION AND CONSULTATION

9.1 LEGAL REQUIREMENTS RELATING TO PUBLIC PARTICIPATION AND CONSULTATION

It is a constitutional requirement to conduct public participation whenever a state or public officer enacts any law, makes or 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 contribute to the process of making public decisions through their involvement. Public participation ought to be inclusive, transparent, and accountable.

Article 174 gives powers of self-governance to the people and enhances their participation in the exercise of the powers of the State in making decisions affecting them and recognizing 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 where the proposed instruments 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 is appropriate, the regulation-making authority shall have regard to all relevant matters, including the extent to which the consultations are:

(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.

9.2 THE PROCESS OF PUBLIC PARTICIPATION AND CONSULTATION

According to Section 5 of the Statutory Instruments Act, Cap. 2A[2], the Board in consultation with the Ministry of Health will identify specific stakeholders whom it engaged in a consultative process. These include the main professional and specialist institutions and individuals who will be directly or indirectly affected by the statutory instruments.

Commented [AM1]: The RIS will be advertised with the Rules and Regulations so this part should be provided before the public participation

CHAPTER 10

IMPLEMENTATION OF THE REGULATIONS

10.1 COMPLIANCE AND IMPLEMENTATION

It is the duty of the regulation-making authority to assess the adequacy of the institutional framework, the legal framework and other incentives through which the Rules and Regulations will take effect and design responsive implementation strategies that make the best use of them.

Implementing and enforcing the Rules and Regulations will be undertaken through the existing institutional framework at National level (the Health Records and Information Managers Board in consultation with the Cabinet Secretary responsible for matters relating to Health) and the County level

[2] 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.

(County Governments through the responsible County Executive Committee Member).

10. 2 RECOMMENDATIONS

Given the above conclusion, it is recommended that Health Records and Information Managers Rules and Regulations, 2025 be adopted:

10. 3 CONCLUSIONS

Based on the analysis in this statement, the HRIM Rules and Regulations 2025, are necessary. The Rules and Regulations provide a framework for adherence to the Digital Health Act and enforcement of the Data Protection Act within the context of health-related data.