



MINISTRY OF HEALTH

REGULATORY IMPACT STATEMENT

FOR

REGULATIONS TO THE DIGITAL HEALTH ACT NO. 15 OF 2023

November 2024

This Regulatory Impact Statement (RIS) has been prepared by the Ministry of Health in accordance with Sections 6 and 7 of the Statutory Instruments Act, Cap 3A.

TABLE CONTENTS

CHAPTER 1	9
INTRODUCTION AND BACKGROUND	9
1.0 INTRODUCTION.....	9
1.1 BACKGROUND.....	10
1.2 PURPOSE OF THE REGULATORY IMPACT STATEMENT.....	11
1.3 SCOPE OF THE REGULATORY FRAMEWORK.....	12
1.4 OBJECTIVES OF THE REGULATIONS.....	14
1.4.1 The Overall Objective.....	14
1.4.2 Specific Objectives.....	14
1.5 JUSTIFICATION FOR THE PROPOSED REGULATIONS.....	15
1.6 REQUIREMENTS OF THE STATUTORY INSTRUMENTS ACT.....	16
CHAPTER 2	17
OBJECTS OF THE DIGITAL HEALTH REGULATIONS, 2024	17
2.1 HISTORY OF DIGITAL HEALTH IN KENYA.....	17
2.2 EXISTING SCENARIO.....	19
2.3 PARADIGM SHIFT.....	19
2.4 CONSTITUTIONAL DISPENSATION.....	20
2.5 THE DIGITAL HEALTH ACT STATUTORY DISPENSATION.....	20
2.5.1 The Digital Health Agency.....	21
2.5.2 Comprehensive Integrated Health Information System.....	22
2.5.3 Roles and Responsibilities.....	22
CHAPTER 3	24
EVALUATION OF THE PROBLEM	24
3.1 IDENTIFIED CHALLENGES.....	25
3.1.1 Uncoordinated and Fragmented Implementation of Digital Health Solutions and Innovations.....	25
3.1.2 Limited Health Data Management Policies.....	25
CHAPTER 4	27
LEGAL AND POLICY FRAMEWORK FOR THE PROPOSED DIGITAL HEALTH REGULATIONS ..	27
4.1 THE CONSTITUTION OF KENYA.....	27
4.2 THE HEALTH ACT, Cap. 241.....	28
4.3 DIGITAL HEALTH ACT, 2023.....	28

4.4	<i>THE KENYA DATA PROTECTION ACT, Cap. 411C</i>	29
4.5	<i>ACCESS TO INFORMATION ACT, Cap. 7M</i>	29
4.6	<i>PUBLIC ARCHIVES, RECORDS AND DOCUMENTATION ACT, Cap. 19</i>	29
4.7	<i>KENYA INFORMATION AND COMMUNICATIONS ACT, Cap. 411A</i>	29
4.8	<i>THE KENYA HEALTH POLICY, 2014-2030</i>	30
4.9	<i>KENYA NATIONAL eHEALTH POLICY, 2016-2030</i>	30
4.10	<i>THE DRAFT TELEMEDICINE STANDARDS AND GUIDELINES, 2023</i>	30
4.11	<i>THE DRAFT KENYA HEALTH DATA GOVERNANCE FRAMEWORK (KHDGF) 2023- 2028</i>	31
4.12	<i>KENYA HEALTH SECTOR PARTNERSHIP AND COORDINATION FRAMEWORK, 2018 -2030</i>	32
4.13	<i>DATA, SYSTEM GOVERNANCE AND CHANGE MANAGEMENT FRAMEWORK, 2018</i>	32
4.14	<i>HEALTH SECTOR UNIQUE IDENTIFICATION FRAMEWORK, 2022</i>	32
4.15	<i>KENYA HEALTH SECTOR DATA QUALITY ASSURANCE (DQA) PROTOCOL, 2014</i>	33
4.16	<i>KENYA HEALTH SECTOR MONITORING AND EVALUATION PLAN, 2019</i>	33
4.17	<i>STANDARDS AND GUIDELINES FOR ELECTRONIC MEDICAL RECORDS SYSTEMS (EMR) IN KENYA</i>	34
4.18	<i>OTHER POLICY INSTRUMENTS IN SUPPORT OF THE DIGITAL HEALTH REGULATIONS</i> 35	
CHAPTER 5		36
AN OVERVIEW OF THE PROPOSED REGULATIONS		36
<i>REGULATION ONE: THE DIGITAL HEALTH (HEALTH INFORMATION MANAGEMENT) REGULATIONS, 2024</i>		36
<i>REGULATION TWO: THE DIGITAL HEALTH ((USE OF E-HEALTH APPLICATIONS AND TECHNOLOGIES) REGULATIONS ,2024</i>		38
<i>REGULATION THREE: THE DIGITAL HEALTH (ESTABLISHMENT AND IMPLEMENTATION OF THE DATA EXCHANGE) REGULATIONS, 2024</i>		40
CHAPTER 6		41
COST-BENEFIT ANALYSIS		41
<i>Matrix of Benefits and Costs on the Digital Health Regulations</i>		44
CHAPTER 7		47
SOCIO-ECONOMIC IMPACTS		47
a.	<i>Improved Healthcare Delivery</i>	47
b.	<i>Empowerment of Patients and Communities</i>	47
c.	<i>Public Health Surveillance and Response</i>	47
d.	<i>Research and Innovation</i>	47

<i>e.</i>	<i>Job Creation and Economic Growth</i>	47
<i>f.</i>	<i>Enhanced Regulatory Compliance</i>	48
<i>g.</i>	<i>Cost Savings</i>	48
CHAPTER 8		49
CONSIDERATION OF ALTERNATIVES TO THE DIGITAL HEALTH REGULATIONS		49
8.1	<i>OPTION ONE: MAINTENANCE OF THE STATUS QUO</i>	49
8.2	<i>OPTION TWO: ADMINISTRATIVE MEASURES</i>	49
8.3	<i>OPTION THREE: DEVELOPING THE PROPOSED DIGITAL HEALTH REGULATIONS, 2024</i>	50
8.4	<i>PREFERRED OPTION</i>	50
CHAPTER 9		53
PUBLIC CONSULTATIONS		53
9.0	<i>LEGAL REQUIREMENTS RELATING TO PUBLIC PARTICIPATION AND CONSULTATION</i>	53
9.1	<i>THE PROCESS OF PUBLIC PARTICIPATION</i>	54
9.2	<i>STAKEHOLDER MAPPING</i>	54
9.3	<i>PUBLIC CONSULTATION APPROACH AND METHODOLOGY</i>	54
CHAPTER 10		55
IMPLEMENTATION OF THE REGULATIONS		55
10.0	<i>COMPLIANCE AND IMPLEMENTATION</i>	55
10.2	<i>CONCLUSION</i>	55
10.3	<i>RECOMMENDATION</i>	55

LIST OF TABLES

Table 1: Benefits and Costs of the Digital Health Regulations.....44
Table 2: Matrix of the impact of options on key sectors 50

ABBREVIATIONS

BETA-	Bottom-Up Economic Transformation Agenda
CR-	Client Registry
CIHIS-	Comprehensive Integrated Health Information System
CECM-	County Executive Committee Member
DPA-	Data Protection
DQA-	Data Quality Assurance
EMRs-	Electronic Medical Records
HIS-	Health Information System
HPTs-	Health Products and Technologists
HIV-	Human Immunodeficiency Virus
ICTs-	Information and Communication Technologies ICT
KHIS-	Kenya Health Information System
KHSSP-	Kenya Health Sector Strategic and Investment Plan
KMHFL-	Kenya Master Health Facilities List
MoH-	Ministry of Health
MHealth-	MHealth-mobile health
M&E-	Monitoring and Evaluation
NHDD-	National Health Data Dictionary
SHR-	National Shared Health Records
NGOs-	Non-Governmental Organizations
PEPFAR-	President's Emergency Fund for AIDS Response
RIS-	Regulatory Impact Statement
SOPs-	Standard Operating Procedures
SDG-	Sustainable Development Goal
WHO-	World Health Organization
UPI-	Unique Patient Identifier
UHC-	Universal Health Coverage

DEFINITION OF TERMS

“Aggregate data”	means health data or information consolidated and stored in a single, central system for ease of access including service statistics or clinical data.
“Archiving”	means the transfer of health data to a less frequently used storage medium.
“Authorized access”	means the legitimate and sanctioned entry, retrieval and processing of data within a system by an individual or an entity that has been granted explicit permission and privileges by a health data controller based on the roles and responsibilities of that individual or entity and the applicable policies governing the system of the health data controller.
“Comprehensive Integrated Health Information System”	means the system administered by the Agency for the collection, collation, analysis, reporting, storage, usage, sharing, retrieval or archival of data related to the state of physical or mental health of a data subject and includes— (a) records on the past, present or future state of the health of a data subject; (b) data collected in the course of registration for, or provision of health services; or (c) data which associates the data subject to the provision of specific health services.
“Data controller”	means a natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purpose and means of processing personal data.
“Data processor”	means a natural or legal person, public authority, agency or other body which processes personal data on behalf of a data controller.
“Digital health solution”	means a digital health application, intervention or initiative and includes digital health technology infrastructure including telehealth systems and electronic health information systems and the provision of education and training support for e-Health initiatives;
“eHealth”	means the combined use of electronic communication and information technology in the health sector including telemedicine;

“Health data”	means data related to the state of physical or mental health of a data subject and includes records regarding the past, present or future state of the health, data collected in the course of registration for, or provision of health services or data which associates the data subject to the provision of specific health services.
“Legacy data”	means information that is stored in formats, technologies or systems that are difficult to access or that have become outdated, obsolete or were developed before the adoption of national standards.
“Personally identifiable information”	means information that may be used to uniquely identify, contact or locate an individual, or may be used with other sources to uniquely identify a person.

CHAPTER 1

INTRODUCTION AND BACKGROUND

1.0 INTRODUCTION

The World Health Organisation (WHO) defines a health system as consisting of all the organisations, institutions, resources, and people whose primary purpose is to improve the health of a population. Such a system includes efforts to influence the determinants of health as well as more direct health-improvement activities¹.

Health systems deliver preventive, promotive, curative, and rehabilitative interventions through a combination of public health actions and the pyramid of healthcare facilities that deliver personal healthcare.

Kenya has made significant strides towards digital transformation with many sectors leveraging technology to enhance the implementation of digital products and services. The health sector has made steady progress in this regard, especially through the implementation of digital solutions to manage, share and use health data².

Traditionally, the country's health sector has relied on paper-based information systems characterized by low-quality data, lack of real-time reports, tedious processes, occasional loss of vital data, inefficiencies in focused care and operational inefficiencies during planning.

Several attempts have been made to digitize the health information system - mostly through partners (in the absence of legal and policy guidance). These attempts have resulted in siloed and disparate systems that have a limited ability to meaningfully exchange health information for focused patient care and planning.

Further, the adoption of technology has been uncoordinated, characterized by fragmented implementation with health sector actors not adhering to basic digital health standards, guidelines, recommendations and digital development principles. These technologies have affected how health data is managed, resulting in multiple disparate systems that have limited ability to exchange data and loss of resources due to inefficiency.³

The eHealth conference held at the Bellagio Center, Italy, between July and August 2008, raised pertinent issues that require sound eHealth policy. This need has also been reaffirmed by the Constitution, the Health Act, Cap. 241, the Data Protection Act, Cap. 411C, the Kenya Health Policy (2014-2030), Vision 2030, the Kenya eHealth Strategy (2011-2017). Collectively, they provide the rationale behind the development of the Kenya Digital Health Act, No. 15 of 2023.

¹ E-health policy

² Draft Kenya Health Data Governance framework

³ Draft Kenya Health Enterprise Architecture

Equally, the Government of Kenya identified healthcare delivery as one of the core pillars of its Bottom-Up Economic Transformation Agenda (BETA). In the Agenda, several commitments towards the delivery of Universal Health Coverage (UHC), are identified, including:

- (a) a fully publicly financed primary healthcare comprising preventive, promotive, curative, palliative and rehabilitative services;
- (b) integrating Information Communication and Technology systems to enhance telemedicine and health management information systems in order to improve efficiency, address fraud and enable patient data portability;
- (c) in collaboration with County Governments, ring-fencing funds for healthcare at the facility level, to enable the availability of funds at the public facility for the improvement of health services;
- (d) setting up an emergency medical treatment fund to cater for emergencies, cancer treatment and referrals; and
- (e) providing a Social Health Insurance Fund coverage for all Kenyans without exclusion, in the policy of “Leaving No One Behind.”

These commitments are in line with the Kenya Vision 2030, which, under the Social pillar, envisions a nation that is healthy and prosperous. The commitments further align with the Sustainable Development Goal (SDG) 3 on “Good Health and Well-Being” which seeks to ensure promote wellbeing and healthy lives for all at all ages.

Additionally, the Kenya Kwanza manifesto identifies digitization as a pillar for the health sector, to enable it to achieve Universal Health Coverage. By adopting digital health technologies, the country can ensure that everyone has access to the care they need, regardless of their location or financial situation.

Several success indicators are to be realized to achieve this, including the reengineering of healthcare services, health financing architecture and the provision of functional, efficient and sustainable digital health infrastructure network across the country.

1.1 BACKGROUND

The Constitution recognizes health as a fundamental human right. Specifically, Article 43(1)(a) stipulates that every person has the right to the highest attainable standard of health, which includes the right to healthcare services, reproductive health and emergency medical treatment. Further, the Constitution provides a legal framework to ensure a comprehensive rights-based approach to the delivery of health services. It obligates every State organ to take legislative,

policy, and other measures, including setting standards to achieve the progressive realization of the rights guaranteed in Article 43.⁴

The Health Act, Cap. 241, recognizes eHealth as a mode of service delivery and goes ahead to direct that the Cabinet Secretary for Health to enact e-legislation that will address key areas including health service delivery using eHealth, in addition to the collection and use of personal health information. Further, the Health Act directs the Ministry of Health to *establish a comprehensive and integrated health information system*⁵.

The Digital Health Act responds to this, by establishing the Digital Health Agency; a comprehensive integrated digital health information system; and a framework for the provision of digital health services. It provides the legal basis for the operationalization and implementation of a comprehensive and integrated health information system. Optimal implementation will result in systematic, coordinated deployment of certified systems that are then interoperable through the shared resources that comprise several registries. Combined, these will be the single source of truth within the health sector. This system enables end-to-end visibility of health processes and seamless sharing and portability of health information. Further, it is central to the implementation of the other pillars identified for the delivery of universal health coverage as it provides real-time data for decision-making, thereby enhancing health service delivery and improving the efficient use of resources.⁶

The establishment of the Digital Health Agency further ensures that there is a dedicated entity fully involved in the technical implementation of digital health in the country. This Agency has several functions which include certification of point-of-care systems, establishment and maintenance of the shared resources, security of the health data within the system and strengthening existing health information systems such as the Kenya Health Information System. It is expected that this will result in high-quality health data that will be used at all levels of the health care system to make evidence-informed decisions and promote innovation, all with the sole objective of improving the quality of health care services and ensuring all Kenyans have access to it as per the aspirations of the Constitution.

Further, the Agency will ensure that health data is managed as per standard data governance principles, thereby promoting one of the overall principles of the Digital Health Act that states health data is a strategic national asset.

1.2 PURPOSE OF THE REGULATORY IMPACT STATEMENT

Sections 6, 7(1) and (2) of the Statutory Instruments Act, Cap. 3A, requires the preparation of a Regulatory Impact Statement (RIS), by the regulation-making authority, for any proposed statutory instrument that is likely to impose significant costs on the community or a part of the

⁴ Constitution of Kenya, 2010

⁵ The Health Act, 2027

⁶ Digital Health Act, 2023

community. It also requires that the regulation making authority, carries out public consultation in developing the proposed regulatory measures.⁷

The Regulation-making Authority for these Regulations is the Cabinet Secretary for Health and the Board, in collaboration with the Digital Health Agency and county governments.

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

- 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 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 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; and
- g) a draft copy of the proposed statutory rule.

The Regulatory Impact Assessment is intended to ensure that regulations are only implemented when there is a justified need and that only the most efficient forms of regulations are adopted. This process involves an assessment of regulatory proposals and allows members of the community to comment on proposed regulations before they are finalized. Such public input provides valuable information and perspectives and improves the overall quality of regulations.

Section 5 of the Statutory Instruments Act also requires that during public consultations, the regulatory-making authority conducts public consultations, drawing on the knowledge of persons having expertise in fields relevant to the proposed statutory instrument and also take measures to ensure that persons likely to be affected by the proposed statutory instrument are given an adequate opportunity to comment on its proposed content.

1.3 SCOPE OF THE REGULATORY FRAMEWORK

The proposed Digital Health Regulations, 2024 (or “Proposed Regulations”) are prepared in accordance with Section 60 of the Digital Health Act, 2023, which mandate the Cabinet Secretary for Health to, in consultation with the Agency and the county governments, develop regulations providing for—

- a) Health information management policies and procedures; ,
- b) the use of e-Health applications and technologies, medical devices and innovations;
- c) data quality and data protection audits; and

⁷ Statutory Instruments Act, 2013

- d) the establishment and implementation of the data exchange component as per the Kenya Health Enterprise Architecture.

The proposed regulations seek to ensure the optimal functioning of the components of the system, including the critical digital health infrastructure provided for under Section 16 of the Act. The regulations⁸ made under this subsection shall provide for the:

- a) administration and maintenance of the enterprise service bus;
- b) application and processing for onboarding to the enterprise service bus;
- c) maintenance of inventory of data controllers of the certified digital health solutions and removal procedure for the enterprise service bus;
- d) establishment and maintenance of National Data Bank and County Health Data Bank established and gazetted by the Cabinet Secretary pursuant to Section 26(1) of the Act;
- e) management of shared or common resources;
- f) establishment of the National Health Data Dictionary established under Section 16(e) of the Act;
- g) establishment of a facility registry that includes telemedicine health providers, Health Worker registry and client registry according to Section 16(e) of the Act;
- h) establishment and publishing of the Kenya Health Enterprise Architecture and the Product Catalogue in line with Section 16(e) of the Act;
- i) development and maintenance of the National Logistics Management Information Services Platform, established through Section 16(e) of the Act, which will be the main reference point in the tracking and tracing of all health products and technologies in the country;
- j) management of the Shared Health Record and the Health Management Information Services Platform for reporting established according to Section 16(e) of the Act;
- k) provision of a comprehensive costing of the healthcare services provided to clients;
- l) certification of digital health solutions in accordance with the Certification Framework developed and published by the Agency;
- m) maintenance of the Kenya Health Data Governance Framework established under Section 21(1) of the Act;
- n) data custodianship and security of health data and network operations command center established according to Section 24(5), ensure the security of the system;
- o) implementation and maintenance of privacy standards across the data life cycle guided by the Access to Information Act, Cap. 7M, the Data Protection Act, Cap. 411C and any other relevant laws, industry best practices and international standards;
- p) archiving of health data, health data sharing, rectification or erasure of personal data, secondary use of health data, data migration, the procedure to access health data from the system and health tourism.

⁸ Digital Health Regulations ,2024

- q) enforcement of e-waste management guidelines issued by the National Environment Management Authority (NEMA);
- r) requesting, processing and disclosure of sensitive personal data in emergencies and disclosure of sensitive personal data of deceased persons;
- s) disclosure of personal health data for market research; and
- t) complaint management.

1.4 OBJECTIVES OF THE REGULATIONS

The objective of the proposed Regulations is to give full effect to the Digital Health Act, 2023. These Regulations focus on key areas under the Act that must be operationalized as a matter of priority to facilitate the attainment of Universal Health Coverage (UHC).

Implementation of the Digital Health Regulations will improve the availability and quality of healthcare services using ICTs. They will also go a long way in providing direction on the adoption and utilization of technologies for the collection, storage, retrieval, analysis and exchange of patients' medical health information in an ethical, efficient, cost-effective, and secure manner. By leveraging eHealth to improve national and county health systems, the health sector will provide affordable and equitable electronic health information and services.

1.4.1 The Overall Objective

The overall objective of these Regulations is to provide for the full implementation of the Digital Health Act, 2023.

1.4.2 Specific Objectives

Specifically, these Regulations will-

- (a) Guide the design, development, operationalize, and maintenance of a Comprehensive Integrated Health Information System; the establishment of registries to create a single source of reference facilitate the collection and analysis of data to inform policy and research in the health sector.
- (b) Provide for management of the core digital systems and the infrastructure required for seamless health information exchange.
- (c) Provide for regulation of processing of health data and in particular, health data that contains sensitive personal data through technological mediums such as telemedicine.
- (d) Facilitate the realization of the right to protection of personal information as guaranteed under Article 31 of the Constitution and the Data Protection Act. It does this by requiring healthcare providers and technology platforms that offer telemedicine to put in place sufficient safeguards, including anonymization and de-identification of sensitive personal data. Such robust data governance guarantees that sensitive patient information is safeguarded from unauthorized use, breach and potential misuse.

- (e) Guide the mechanisms for interconnectivity between county information systems and the national system. This will assist both levels of government in coming up with consumer-focused and prevention-oriented care at all levels of healthcare services, which will ultimately reduce the disease burden in the country.

Once implemented, the proposed regulations ought to enhance service delivery within the health sector, as it is expected that there will be timely sharing of credible information on patient care and effective coordination among health facilities resulting in improved patient outcomes and streamlined health service delivery from treatment of patients to the settlement of claims by the health insurance services.

1.5 JUSTIFICATION FOR THE PROPOSED REGULATIONS

The Proposed Regulations will provide a framework for the provision of digital health services and establish 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 proposed Regulations will facilitate comprehensive implementation of the Act, hence facilitating a people-centered quality health service delivery; ensuring data collection and reporting at all levels of health care provision; enabling secure health data sharing for timely and informed inter-facility health service delivery; facilitating data processing and use for informed decision-making at all levels; safeguarding the privacy, confidentiality, and security of health data for information sharing and use; and guiding the tracking and tracing of health products and technologies in the country, among others.

They will guide the establishment of an integrated digital health system, hence, addressing 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.

Once fully implemented, the Regulations will give Kenyans the ability to have more control over their personal data, particularly in health facilities, as they must provide consent before the collection, processing, and sharing of their personal health-related information. There will also be enhanced patient safety, especially in telemedicine and e-health platforms that have been largely unregulated.

This will enhance service delivery within the health sector as there will be timely sharing of credible information on patient care between healthcare providers, which will ultimately improve health outcomes in the country and help with early diagnosis hence reducing the disease burden. This way, there will be enhanced patient safety and improved safety and security of patient information.

The Regulations further address the challenges that the health sector faced when the Data Protection Act, came into operation (not being fully compliant on matters of data protection).

These challenges were a daily occurrence as the health sector handles sensitive patient data whose protection requires more safeguards. The Act therefore reduces the challenges related to privacy concerns and data breaches that are now more prevalent in the 21st century.

1.6 REQUIREMENTS OF THE STATUTORY INSTRUMENTS ACT

Under Sections 6 and 7 of the Statutory Instruments Act, if a proposed statutory instrument is likely to impose significant cost in the community, or part of the community, the regulation-making authority shall, before making the statutory instrument, prepare a regulatory impact statement.⁹

A Regulatory Impact Statement shall contain;

- 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 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 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; and
- g) a draft copy of the proposed statutory rule.

The Ministry of Health prepared the Regulations for the Digital Health Act as the statutory instruments necessary to operationalize the Digital Health Act, 2023. The Regulations were subjected to stakeholders' comments and public participation as required by Section 5 of the Statutory Instruments Act. These comments were used to enrich the Regulations.

⁹ Statutory Instruments Act, Cap 3A

CHAPTER 2

OBJECTS OF THE DIGITAL HEALTH REGULATIONS, 2024

The general objective of these Regulations is to give effect to Sections 60 of the Digital Health Act No. 15 of 2023. The specific objectives¹⁰ are to-

- (a) provide for the principles, procedures and standards for the establishment and maintenance of a comprehensive integrated health information system;
- (b) promote innovation, safe, efficient and effective use of technology for healthcare, including continuity of care, emergency and disaster preparedness and disease surveillance;
- (c) establish a regulatory framework for the e-Health ecosystem data lifecycle;
- (d) provide for privacy, confidentiality, and security of health data;
- (e) develop standards for the provision of m-Health, telemedicine, and e-learning;
- (f) establish a regulatory framework for e-waste management; and
- (g) to provide for the administration, management and provision for the safe and secure transfer of personal, identifiable health data and client's medical records to and from health facilities within and outside the country.

2.1 HISTORY OF DIGITAL HEALTH IN KENYA

As early as 1972, Kenya's Ministry of Health (MoH) recognized the need for a robust health information system, over the next decade. The MoH led Kenya's health sector on a journey of coordination and development, decentralizing the health information system. However, it wasn't until the mid-1980s to early 2002 that Kenya witnessed a surge in the implementation of electronic health information systems (HIS), leading to a proliferation of non-standardized and interoperable systems.

Before 2010, Kenya's health sector had multiple Electronic Medical Records (EMRs) existing in the country. The Ministry of Health developed EMR standards and guidelines and conducted an assessment around the same time and found only four EMRs conformed to those standards and guidelines.

Results from a field study in 2016 and a meta-analysis of articles on eHealth published in 2017 indicate that there has been a significant increase in the uptake of e-health interventions since the first initiative recorded in 2001.

After devolution, there was accelerated deployment of eHealth interventions. From 2012 to 2015, these EMRs were rolled out using the United States President's Emergency Fund for AIDS Response (PEPFAR). By 2016, there were over 642 health facilities using EMRs for data capture and reporting in large HIV clinics. The EMR systems are integrated with a health information

¹⁰ Digital Health Regulations, 2024

superhighway through the National Client Registry (CR), National Health Data Dictionary (NHDD) and the National Shared Health Records (SHR).

Most of the eHealth projects implemented are mostly funded by development partners and Non-Governmental Organizations (NGOs), *raising the issue of ownership and sustainability*. This creates the need for an eHealth policy and regulatory framework that guides ownership of eHealth projects.

The COVID-19 pandemic acted as a catalyst for innovation leading to solutions like ChanjoKE and other disease-surveillance digital health tools. The Konza Technopolis, which provides a cloud-compute environment, ensures that the systems can interoperate and therefore provide a more synergistic approach to the digitization of the health system.

The Kenyan Government prioritized digital health programs under the Third Medium Term Plan 2018-2022. In addition, the Kenya Kwanza manifesto identifies digitization as a pillar for the health sector to enable achieving Universal Health Coverage. By adopting these digital health technologies, the country can ensure that everyone has access to the care they need, regardless of their location or financial situation. This may be attributed to the government’s recognition of ICT as a key enabler to social, economic, and political development. It is from this long-term blueprint that policies, strategy documents, legislation, and regulations need to be developed and operationalized.

The Digital Health Act, 2023, provides for the establishment of the Digital Health Agency that provides a framework for the provision of digital health services and the establishment of a comprehensive integrated digital health information system.

Digitization is capital-intensive undertaking (in terms of hardware and software). For this reason, the Government of Kenya through the Ministry of Health, has over the years collaborated with different partners to ensure that the digitization agenda is articulated. Kenya's commitment to

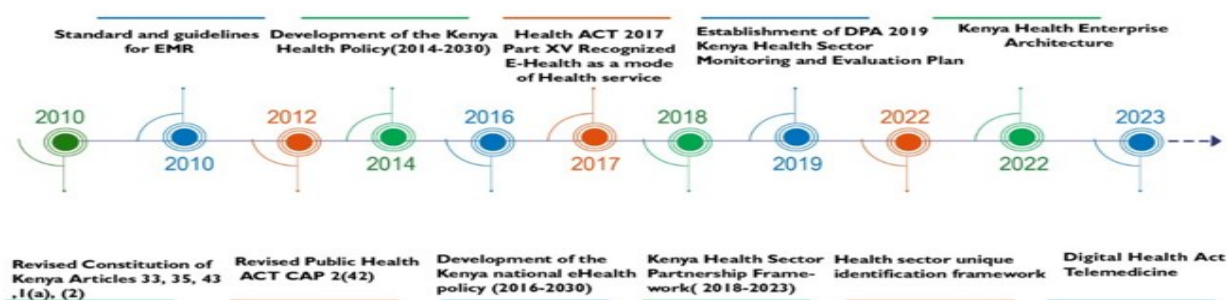


Figure 1: Development timeline of governance legislation and policy documents in Kenya.

¹¹The future holds the promise of artificial intelligence, where AI-enabled digital health systems

¹² Draft Kenya Health Enterprise Architecture

are emerging to further enhance healthcare delivery. We are leveraging artificial intelligence and machine learning to start to predict trends for patients. These systems are expected to drive critical reforms in health service delivery.

2.2 EXISTING SCENARIO

Currently, e-health is provided for under the Health Act. It provides a legal framework for the regulation and management of health information systems. Section 104 of the Health Act, mandates the Cabinet Secretary for Health to ensure the enactment of e-health legislation.

The Digital Health Division Unit falls under the stewardship of the Directorate of Health Financing, Digital Health, Policy, and Research in the Ministry of Health. Currently, the link between the Division and the Ministry of ICT (MoICT) is not well structured, making it difficult to assess, monitor and regulate eHealth systems operating in Kenya. Furthermore, the ministries do not maintain a centralized registry of all eHealth projects under implementation in Kenya.

To transform the country into a middle-level economy, the government has initiated long-term development strategies that recognize Science, Technology and Innovation (ST&I) as the drivers to the realization of Vision 2030 and Sustainable Development Goals (SDGs). The Regulations for the Digital Health Act will provide a governance framework for Digital Health service provision and establish comprehensive and integrated health information systems that will direct, institutionalize and regulate the practice of eHealth in Kenya.

2.3 PARADIGM SHIFT

The Regulations under the Act have given a focus on key areas under the Act that must be operationalized as a matter of priority to facilitate the attainment of Universal Health Coverage (UHC) by facilitating evidence-based decision-making and innovation. Accordingly, they enforce interoperability of health information systems, standardization of Health records and foster innovation towards person-centric service delivery.

Digital health can empower communities and enable personalization of care for the patient/client resulting in overall improved quality of care. The Act provides for health data portability as a function that the Agency should implement. This is envisioned to be done through the implementation of a client portal that enables one to access their health data. It is expected that this will be a critical step towards empowering individuals to take charge of their health.

The era of asking patients to purchase small exercise books for recording their health data, as typically happens in public primary health facilities, is now behind us. Instead, we look forward to the patient having access to their health data in an electronic format and even determining who gets to access for the purpose of provision of care.

Further, the establishment of the Shared Health Record as a shared resource will ensure that every Kenyan can access health care in any part of Kenya. No patient should have to recall their

medical history. Rather, this information will be accessible in a digital shared health record format that will enable one to access health services hence promoting health service continuity.

Digital health will therefore contribute to the growth of the health sector through increased access to health care, innovations such as telemedicine and empowered individuals and communities that take charge of their health. Additionally, it will lead to improved performance due to the use of real-time data for decision-making and increased efficiency. This should result in a healthier population that is productive and a better use of resources for a holistic health system.

2.4 CONSTITUTIONAL DISPENSATION

The Constitution, under the Bill of Rights, in Article 43(1)(a) provides for socio-economic rights and gives citizens the right to the highest attainable standards of healthcare. The Constitution provides a legal framework to ensure a comprehensive rights-based approach to the delivery of health services. It obligates every State organ to take legislative, policy and other measures, including setting standards to achieve the progressive realization of the rights guaranteed in Article 43¹².

According to the Tracking Universal Health Coverage 2023 and Global Monitoring Report 2015, Kenya's UHC Service Coverage Index (SCI) was 53 as compared to the global average index of 65 (the 2030 target is 100). These Regulations will accelerate the realization of UHC by integrating Information Communication and Technology systems to enhance access to high standards of healthcare, , and health management information systems to improve efficiency, address fraud and enable patient data portability while ensuring the protection of the rights of confidentiality on information relating to family and private affairs and the right to access information held by the State or held by another person when required for the exercise or protection of another right.¹³

2.5 THE DIGITAL HEALTH ACT STATUTORY DISPENSATION

The Act provides a framework for the provision of digital health services and establishes a comprehensive integrated digital health information 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 is intended to generally manage the core digital systems and the infrastructure required for seamless health information exchange. Having an integrated system addresses the challenges posed by

¹² Constitution of Kenya 2010, Article 43

¹³ Constitution of Kenya 2010, Article 35

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 decisions¹⁴.

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.

2.5.1 The Digital Health Agency

The Digital Health Agency was established by the Digital Health Act, 2023. The Agency is required to develop, operationalize, and maintain a Comprehensive Integrated Health Information System, establish registries to create a single source of truth; facilitate collection and analysis of data to inform policy and research in the health sector; strengthen the existing health information systems; certify digital health solutions based on best practices and standards, and to advise the Cabinet Secretary on matters related to digital health.¹⁵

This mandate is to be carried out in consultation with other statutory bodies, at appropriate levels, to create a single source of truth in respect of clients, health facilities, healthcare providers, health products and technologies.

The Agency will perform the functions stipulated in the Digital Health Act to provide a framework for the provision of digital health initiatives . These functions include:

- a. To promote the adoption of best practices and standards for digital health that facilitate data exchange,
- b. To establish a system of shareable and portable personal health records, and ensure health data portability,
- c. To facilitate collection and analysis of data to inform policy and research in the health sector,
- d. To promote the development of enterprise-class health application systems, strengthen existing health information systems by ensuring their conformity with the prescribed standards and integration with the comprehensive integrated health information system,
- e. To develop and implement the infrastructure for health data exchange of health information securely,
- f. To support the development and implementation of standards for enhanced interoperability,
- g. To maintain, in collaboration with the counties and other statutory authorities, the technological infrastructure necessary for the core digital health services,

¹⁴ Digital Health Act, 2023

- h. To undertake resource mobilization for the implementation of health digitization in the country,
- i. To certify digital health solutions based on best practices and standards and advise the Cabinet secretary on matters related to digital health.

2.5.2 Comprehensive Integrated Health Information System.

The main objectives of the system shall be to-

- (a) facilitate people-centered quality health service delivery;
- (b) facilitate data collection and reporting at all levels;
- (c) enable secure health data sharing to ensure timely and informed interfacility health service delivery;
- (d) facilitate data processing and use for informed decision-making at all levels, including-
 - (I) at individual patient level;
 - (II) for public health purposes; and
 - (III) for resource allocation and management in the health sector;
- (e) safeguard the privacy, confidentiality and security of health data for information sharing;
- (f) serve the health sector and facilitate - progressively and equitably – the realization of universal health coverage, to achieve the highest attainable standard of health;
- (g) ensure standardization of health data management; and
- (h) facilitate the tracking and tracing of health products and technologies in the country.

The Agency adopts relevant internationally accepted standards, procedures, technical details, best practices, and formalities for effective implementation of the system.

2.5.3 Roles and Responsibilities

The Constitution, under Article 6(2) requires governments at both levels to conduct their mutual relations based on consultation and cooperation. This article is operationalized by the establishment of the Intergovernmental Relations Act, Cap. 265F, which established the Council of Governors, as a forum for consultations and cooperation between the County and National governments.

These Regulations assign roles and responsibilities to guide their implementation. Custodianship of health data will be shared between the National and County Governments based on the principles of cooperation and coordination as outlined in the Health Act and the various legislation regulating the relationships and functions of the County and National Governments.

The Digital Health Agency is the overall custodian of the National Health Data and its responsibilities include coordination of Digital Health development, implementation, evaluation and review at the national level. ¹⁶

¹⁶Digital Health Regulations, No. 15 of 2024

A key shared function will be the establishment and maintenance of a National Registry of Health Data Controllers and processors. This role will be implemented by the Cabinet Secretary (CS) responsible for Health and the County Executive Committee Member (CECM) for Health, respectively.

The County Executive Committee Member (CECM) for Health will be the controller of health data at the county level, they will have overall responsibility including sharing those data with other counties and the National level.

The Ministry of Information and Communications Technology (MoICT) is one of the crucial ministries whose responsibilities include the provision of technical support and advice required during the development and implementation of these Regulations as well as Monitoring and evaluation of organizational compliance with standards and guidelines for Digital Health infrastructure, device specifications and software.

The Office of the Data Protection Commissioner (ODPC) is the primary regulatory authority responsible for overseeing data protection and ensuring compliance by data controllers and processors. This office will offer regulatory oversight to ensure the privacy and security of personal health information and address and resolve complaints related to data breaches and non-compliance with data protection Regulations.

The private sector, including healthcare providers and insurers, plays a crucial role in the implementation and operationalization of digital health Regulations. They have the responsibility of ensuring their health information and digital systems comply with these regulations and guidelines set by the ODPC. As data controllers, they have the responsibility of implementing data protection measures to safeguard patient information, including encryption, access controls, and secure data storage.

Digital health solution vendors and innovators will create and supply digital health technologies and solutions interoperable with the national integrated system and have the responsibility of ensuring the solutions they provide adhere to the Digital Health Agency certification framework, comply with data protection regulations, and meet the needs of healthcare providers and patients.

The public and clients are the data owners and the end-users of digital health services and technologies. They have the responsibility of ensuring informed consent for the collection, use and sharing of their health data including safeguarding security and protection of personal data.

CHAPTER 3

EVALUATION OF THE PROBLEM

To transform the country into a middle-level economy, the government has initiated long-term development strategies that recognize Science, Technology and Innovation (ST&I) as the drivers to the realization of Vision 2030 and Sustainable Development Goals (SDGs).

Since 2010, the nation has witnessed accelerated deployment of eHealth interventions. This trend may be attributed to the government's recognition of ICT as a key enabler to social, economic, and political development. It is from this long-term blueprint; that policies, strategy documents, legislation, and standards need to be developed and operationalized.¹⁷

Results from a field study in 2016 and a meta-analysis of articles on eHealth published in 2017 indicate that there has been a significant increase in the uptake of eHealth interventions since the first initiative recorded in 2001. In terms of investment and ownership, the study revealed that most eHealth projects implemented in Kenya were mostly funded by development partners and Non-Governmental Organizations (NGOs) raising the issue of ownership and sustainability.

Kenya's digital health landscape encompasses robust health information systems, data protection laws and a commitment to improving health outcomes while safeguarding sensitive information. The Proposed Digital Health Regulations are alive to the devolved system of government in the constitution that outlines healthcare functions assigned to the national and county governments. The national level has overall stewardship; policy formulation, standards and regulations, capacity building and national referral facilities, while the counties are responsible for policy implementation and service delivery. The levels conduct their activities based on mutual consultation, collaboration, and cooperation.

Kenya has a mix of public (41%), private (49 %), and faith-based and NGO (10 %) health service providers (KMHFL, 2023). The country has made massive investments in health infrastructure, which has improved access to and coverage of health services in the country, albeit with substantial variation across counties.

The number of government health facilities increased by 33.6 percent from 4,456 to 5,953 nationally from 2013 to 2018. As the number of health facilities increased, access to health services also improved, especially in previously neglected and remote areas.

Several challenges hinder the successful implementation of most eHealth systems in Kenya. Some of the limitations include poor infrastructure, low literacy, inadequate technical expertise, unreliable power supply, limited funding, and lack of government involvement in most eHealth projects. Therefore, to accelerate the seamless integration of eHealth into conventional healthcare systems, WHO/ITU's Global Observatory Survey report (2014) points to the need for developing countries to formulate eHealth strategies for overcoming these challenges. Some

¹⁷ Kenya eHealth meta-analysis of articles on eHealth published in 2017.

of the strategies and interventions being applied include broadband connectivity, **policy formulation**, setting eHealth standards, creating private-public partnerships, and capacity building.

3.1 IDENTIFIED CHALLENGES

The digitalization of health information is poised to revolutionize the safeguarding of individuals and communities against various challenges across the health data lifecycle. This transformation will address key issues such as unauthorized access to private data, inappropriate use or collection of sensitive personal information and safeguarding the rights of individuals to access, update, and own their personal data.

Despite the limitations in the implementation of e-health in Kenya, the Ministry of Health has made significant strides towards legislating digital health data, with the latest being the enactment of the Digital Health Act. A comprehensive digital health regulation framework will clearly outline the roles and responsibilities of all actors involved in handling and managing data, thereby eliminating any ambiguities and loopholes that would compromise the safe and ethical use of health data.

3.1.1 Uncoordinated and Fragmented Implementation of Digital Health Solutions and Innovations.

Kenya's health sector has implemented various digital health solutions to enhance the delivery of service in various programmes in the health sector mostly funded by implanting partners. Many health sector actors did not adhere to essential foundational digital health standards, guidelines, and recommendations, including best practices such as those espoused by the principles of the Digital Health Act. This Regulations will contribute to and further reinforce Government strategies aimed at consolidating and optimizing investments and effectiveness of digital health in a sustainable manner.

3.1.2 Limited Health Data Management Policies

Most organizations acknowledge that data management policies exist in their organizations. Some policies mentioned include the Monitoring and Evaluation (M&E) framework, Health Information System policy, data sharing agreements, data use guidelines, Standard Operating Procedures (SOPs), and MoH data management guidelines. In most organizations, the policies prioritize data access, followed by data use and then data sharing. The policy documents in the sampled organizations mainly cover general health data, while some deal with program-specific data e.g. HIV, and a smaller portion covers other elements of health systems. Policy coverage has been limited to organizational-level policies, partner organization policies, and a small number of national and regional policies. Digital Health Regulations 2024 will provide a clear structure for implementing guidelines and policies with assigned roles and responsibilities in data management.

3.1.3 Geographical Barriers and Healthcare Infrastructure Disparities

In Kenya, disparities in access to healthcare services exist between urban and rural areas, leading to unequal healthcare outcomes. A centralized digital health system could bridge this gap by enabling telemedicine and remote healthcare services, extending quality care to underserved populations.

The diverse geography poses challenges for accessing healthcare, particularly in remote or rural areas. A decentralized digital health system can facilitate remote consultations, telemedicine, and mobile health services, improving access to healthcare for underserved populations.

Disparities in healthcare infrastructure between urban and rural areas contribute to inequalities in healthcare access and delivery. A centralized digital health system that supports eHealth can help bridge this gap by enabling the delivery of healthcare services and information via digital platforms, reducing the reliance on physical infrastructure.

3.1.4 Limited Interoperability

The existing health information systems in Kenya often lack interoperability, hindering seamless data exchange between different healthcare providers and systems. A centralized digital health system would facilitate interoperability standards, allowing for efficient sharing of patient information across the healthcare ecosystem.

3.1.5 Sub-Optimal Data Security

With the increasing digitization of health records, the risk of data breaches and unauthorized access to sensitive patient information becomes a significant concern. A centralized digital health system could implement robust security measures to safeguard patient data, including encryption, access controls and regular security audits.

3.1.6 Limited Healthcare Infrastructure Resulting in Inefficient Healthcare Delivery

Many healthcare facilities in Kenya face challenges such as inadequate infrastructure and medical equipment, which can impact the quality of care delivered. A centralized digital health system could leverage technology to overcome these challenges by enabling virtual consultations, promoting Service Linkage, and resource optimization.

Manual processes and paperwork often contribute to inefficiencies in healthcare delivery, leading to delays and errors in patient care. A centralized digital health system would automate the referral process through patient data portability and enable real-time access to patient information, enhancing the efficiency and effectiveness of healthcare delivery.

CHAPTER 4

LEGAL AND POLICY FRAMEWORK FOR THE PROPOSED DIGITAL HEALTH REGULATIONS

An evaluation of the legal and policy frameworks related to the Digital Health Act intended to bring out the context and legal environment within which the Proposed Regulations are being developed. Regulatory processes should be structured so that all regulatory decisions rigorously respect the principles of the ‘rule of law’. This means that there should be explicit responsibility for ensuring that all regulations are authorized by legislation and are consistent with the supreme law and treaty obligations. In addition, they should complement other legal requirements and ensure statutory harmony of the entire statute book.

4.1 THE CONSTITUTION OF KENYA

The Constitution provides the overarching legal framework to ensure a comprehensive rights-based approach to health services delivery. It sets out the general rights and duties that a public body is expected to adhere to and the values of equity, social justice, equality, inclusiveness, and public participation.

More specific rights and duties are enshrined in the Bill of Rights under Chapter Four of the Constitution. Article 43(1)(a) provides that every person has a right to the highest attainable standard of health, which includes the right to reproductive health rights. It further states that a person shall not be denied emergency medical treatment.

Further, Article 31 stipulates that every individual has a right to not have the information relating to their family and private affairs unnecessarily disclosed and that every citizen has a right to access information¹⁸ held by the State and held by another person and required for the exercise or protection of another right.

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 under Article 43. 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. It is to fulfil these constitutional obligations that the Cabinet Secretary for Health, in consultation with the Digital Health Agency Board, has drafted these regulations.

¹⁸ Article 35, Constitution of Kenya

4.2 THE HEALTH ACT, Cap. 241

Section 104 of the Health Act, among others, directs the Ministry of Health to develop guidance on the administration of health information banks including interoperability framework, data interchange and security the collection and use of personal health information, management of its disclosure, and protection of patient privacy. The Digital Health Regulations are oriented towards promoting the use of health information systems to improve health outcomes and health system performance.

The Regulations recognize the critical role of reliable and timely health information in effective decision-making, planning, and management of the health system at all levels. They emphasize the importance of interoperability and integration of health information systems across different levels of the health system to ensure the seamless sharing of health information.

These Regulations establish a unified health system, coordinate the inter-relationship between the national government and county government health (information) systems, and provide for the regulation of healthcare services and healthcare service providers, health products and technologies. They recognize e-health as a mode of health service and requires the establishment and maintenance of a comprehensive integrated health information system by the Ministry of Health.

4.3 DIGITAL HEALTH ACT, 2023

The Digital Health Act establishes a Digital Health Agency whose mandate includes maintaining the Comprehensive Integrated Health Information System, the digital shared utilities, the development and implementation of standards, and the adoption, implementation and maintenance of digital health solutions.

This Agency is mandated to lead and coordinate investments, in the adoption and use of digital health interventions in Kenya and will be the custodian of health data in the country. In consultation with the Ministry of Health, it will regulate the capture, storage, and sharing of information relating to patients, ensure secure, confidential transmission of data and promote the use of health data for public good.

The Digital Health Act contains provisions that mandate the MoH, in consultation with the Agency, to maintain a registry of data controllers, who are obligated to ensure that the integrity of health data is maintained, and that data is shared between healthcare providers, and between patients and their healthcare providers. The Act also establishes guidelines for the administration of mobile health services and a Framework for efficient interoperability of the various e-health systems and services. Additionally, it outlines rules for accessing and using health information for health research purposes of Kenya's digital health ecosystem in an enterprise.

The Digital Health Regulations 2024 will facilitate the proper implementation of this Act. In this context, the Regulations describe how digital health solutions, infrastructure and standards in the health sector will be organized and how the Digital Health Agency will intersect with other

health governance structures into a digital health enterprise designed to facilitate the attainment of Universal Health Coverage to receive quality, real-time health data.

4.4 THE KENYA 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.

This Act recognizes the sensitive nature of health data and provides for additional safeguards and restrictions on its collection, use, and disclosure to protect individuals’ privacy and confidentiality.

Sections 25, 31, and 46 of the Digital Health Act regulate the collection, processing, storage, maintenance, retention and safeguarding the confidentiality of personal health information. This conforms to the provisions and safeguards laid out in the Data Protection Act.

4.5 ACCESS TO INFORMATION ACT, Cap. 7M

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

These regulations give effect to the Digital Health Act by providing a guideline on the provision of access to health information or data in compliance with Access to Information Act.

4.6 PUBLIC ARCHIVES, RECORDS AND DOCUMENTATION ACT, Cap. 19

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

The Digital health regulations are aligned to the Public Archives, Records and Documentation Act.

4.7 KENYA INFORMATION AND COMMUNICATIONS ACT, Cap. 411A

The Kenya Information and Communications Act provides for the legal recognition of information or data if that information is made available in an electronic form and is accessible for be usable for a subsequent reference. It also enforces the retention of electronic records and information in its original form.

- Section 83G: Defines electronic records as legal records.

- Section 83H: Provides for the period of retention of electronic records.
- Section 83I: Requires retention of information in its original form.

These have been some of the guiding principles in the development of Digital Health regulations.

4.8 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 limitations in the regulatory and resource capacity and utilisation have constrained the health sector's ability to harness fully the existing technology to manage most of the direct causes of ill health and death. The critical role of reliable and timely health information in effective decision-making, planning and management of the health system at all levels is also underscored. The policy also emphasizes the importance of interoperability and integration of health information systems across different 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. Further, it 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 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.

4.9 KENYA NATIONAL eHEALTH POLICY, 2016-2030

This policy is geared towards attainment of the highest standard of health through adoption and use of ICT. Its main goal is to improve the availability and quality of healthcare services through the use of ICTs and provide direction for the adoption and utilization of technologies for collecting, storing, retrieving, analyzing and exchanging patients' medical health information in an ethical, efficient, cost-effective, and secure manner. The policy promises to ensure that the health sector will employ a patient centric approach to the management and use of electronic data in a way that will guarantee confidentiality, integrity, and privacy of patients at all times.

4.10 THE DRAFT TELEMEDICINE STANDARDS AND GUIDELINES, 2023

The Ministry of Health has developed draft guidelines for mobile health (mHealth) systems, which include telemedicine, a service that has not previously been offered in Kenya. These draft guidelines aim to provide a framework for providing telemedicine services in a safe, effective and ethical manner.

The draft guidelines cover a range of topics, including the regulatory framework, clinical governance, privacy and confidentiality, technical standards and patient safety. They guide issues such as informed consent, clinical documentation, prescribing medication and emergency teleconsultations.

4.11 THE DRAFT KENYA HEALTH DATA GOVERNANCE FRAMEWORK (KHDGF) 2023- 2028

The draft framework was developed against the backdrop of optimal digitization within the health ecosystem as a critical pillar for the attainment of Universal Health Coverage. It is alive to the fact that the use of technology has its immense benefits on the one hand, but, on the other hand, introduces potential risks and exposures. This framework therefore, provides structure and guidance for the management of 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 aspects such as privacy protection, transparency, and equitable utilization to ensure the integrity and reliability of health data. The principles have been referenced and contextualized in these 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 Draft Kenya Health Data Governance Framework guides the management of data security risks, particularly relating to unauthorized access to and use of sensitive health information. Additionally while making reference to the Data Protection Act and the Digital Health Act, 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.

4.12 KENYA HEALTH SECTOR PARTNERSHIP AND COORDINATION FRAMEWORK, 2018 -2030

The coordination framework recognizes that the primary responsibility for governance and coordination of all health-related activities carried out by all actors in the health sector in Kenya, lies with the Ministry of Health. Its vision is the realization of a healthy, productive, and globally competitive nation and it is on a mission to build a progressive, responsive and sustainable healthcare system for the accelerated attainment of the highest standard of health for all Kenyans.

The Kenya Health Sector Partnership and Coordination Framework 2018-2030, represents a joint effort by all health sector stakeholders (national and county governments, development partners, implementing partners and private healthcare providers) on how to better coordinate and align efforts towards improving the health of all Kenyans.

It takes into account the devolved system of governance in Kenya and the health sector in particular and proposes structures that bring together partners and stakeholders at different levels to plan and budget together, implement and jointly review progress and be accountable for the ensuing results.

The framework thus represents the aspirations and obligations that all stakeholders have agreed to, which allows for joint efforts towards the attainment of the health agenda as elaborated in the Constitution.

4.13 DATA, SYSTEM GOVERNANCE AND CHANGE MANAGEMENT FRAMEWORK, 2018

This Framework provides specifications of decision rights and accountability to encourage desirable conduct in the valuation, creation, storage, use, archiving, and deletion of data and information. It includes the processes, roles, standards, and metrics needed to effectively and efficiently use data and information to enable the health sector to achieve its goals. This Framework applies to data, information systems governance, and the change management process. This Framework seeks to ensure that appropriate controls are applied to data processes and that data is collected, used and reported in line with its legislative and other compliance obligations.

4.14 HEALTH SECTOR UNIQUE IDENTIFICATION FRAMEWORK, 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 in order to provide quality, focused healthcare. This Framework seeks to ensure there is improved medical record-keeping, to respond to the uptake of digitization by more health facilities. This will in turn lead to progressive advancement of the health of Kenyans.

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 forward towards 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.

4.15 KENYA HEALTH SECTOR DATA QUALITY ASSURANCE (DQA) PROTOCOL, 2014

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 health data 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; and
- implementing data quality improvement strategies.

The DQA guideline seeks to verify data quality components including reliability, accuracy, precision, completeness, timeliness, integrity and confidentiality on standard program level output indicators.

4.16 KENYA HEALTH SECTOR MONITORING AND EVALUATION PLAN, 2019

The Kenya Health Sector Monitoring and Evaluation Plan, seeks to evaluate the implementation of the Kenya Health Sector Strategic Plan 2018–2023, Draft Road Map Towards Universal

Health Coverage in Kenya 2018–2022 and Kenya Primary Health Care Strategic Framework 2019–2024, which intended to improve access to high-quality health services for the population without it leading to financial catastrophe.

Chapter 6 of the plan provides information on monitoring and evaluation, which is based on the national M&E Framework. The primary objective of the M&E Framework is to enhance joint accountability within the health sector. To achieve this, the capacity to generate information, validate, analyze, disseminate and use data for decision-making will be strengthened at the national and county levels. The common M&E Framework focuses on attaining the following three goals:

- i. supporting the establishment of a common data architecture;
- ii. enhancing the sharing of data and promoting the use of data for decision-making; and
- iii. improving performance monitoring and review processes.

4.17 **STANDARDS AND GUIDELINES FOR ELECTRONIC MEDICAL RECORDS SYSTEMS (EMR) IN KENYA**

This policy document was developed to guide implementers of EMR systems as these systems are increasingly being adopted in Kenya to improve medical record management, health program management, and the quality of patient care. These standards and guidelines provide guidance for EMR system developers and implementers, as well as health facilities in Kenya that are contemplating or currently using EMR systems to manage patient data.

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.

4.18 OTHER POLICY INSTRUMENTS IN SUPPORT OF THE DIGITAL HEALTH REGULATIONS

- (a) **Universal Health Coverage Policy:** Kenya's Universal Health Coverage (UHC) policy aims to provide affordable healthcare services to all citizens in response to the Constitution, which guarantees all citizens the right to quality health care. It underscores the critical need of digitization of health data as a crucial component of modern healthcare systems, including those aiming for universal coverage. The government has been actively pursuing digitization initiatives in various sectors, including healthcare. This includes efforts to digitize health records, implement electronic health information systems, and utilize mobile health technologies to reach underserved populations. These regulations can help improve data management, facilitate better decision-making by healthcare providers, and enhance patient care.
- (b) **Health Sector Strategic and Investment Plan:** The Kenya Health Sector Strategic and Investment Plan (KHSSP) outlines the government's priorities and strategies for improving healthcare delivery, including efforts related to the digitalization of health records. Initiatives such as the Kenya Health Information System (KHIS) have been developed to digitize health records and facilitate better data management within the healthcare system. Additionally, the government has promoted the use of mobile health (mHealth) technologies to reach remote and underserved populations and improve access to healthcare services.
- (c) **Strategic and action plans:** Some of the strategic and action plans that form the foundation of the Digital Health Regulations include Sustainable Development Goals (SDGs), Kenya eHealth Strategy (2011-2017), Kenya Health Sector Strategic and Investment Plan (2014-2018), Vision 2030, and the National ICT Master Plan.
- (d) **Global eHealth standards:** Several standards have been developed to ensure interoperability, security, quality and meaningful use of ICTs in healthcare.

CHAPTER 5

AN OVERVIEW OF THE PROPOSED REGULATIONS

RE:
MA

In exercise of the powers conferred by **section 60** (a) of the Digital Health Act No.15 of 2023 the Cabinet Secretary for Health in consultation with the Board of the Digital Health Agency and the County Governments makes the Digital Health (Health Information Management) Regulations of 2024 to give effect to the provisions of the Act by ensuring the safe management of health information. The regulations apply to:

- (a) management of health information and health data;
- (b) processing of personal health data; and
- (c) handling of complaints arising from the use, access and management of health information.

These regulations preside the management, security, privacy, archiving, migration, sharing, and access of health data in Kenya, as well as the management of complaints related to these processes. Below is a summary of the provisions;

1) The Kenya Health Data Governance Framework:

The Kenya Health Data Governance Framework is established as the authoritative guide for managing health data, including its collection, access, sharing, and use. The framework outlines principles of data governance, custodianship responsibilities, data governance structures, and procedures for managing health data throughout its lifecycle.

The Cabinet Secretary, in collaboration with the Agency and stakeholders, will regularly update the framework to align with best practices and industry standards and that the Agency is responsible for ensuring compliance with the framework by health data controllers and processors.

2) Data Custodianship:

The Agency is the custodian of all health data in Kenya, maintaining a registry of data controllers, an inventory of health data, and ensuring data submission in the proper format. It will maintain the National Health Data Bank and provide access to authorized controllers and processors.

3) Data Security:

The Agency will implement security measures, including encryption and access controls, and maintain public portals for data access and management. This will be achieved through compliance with information security standards and continuous monitoring.

Users of the system must adhere to security requirements outlined in the Certification Framework for digital health solutions. The Agency will maintain and mitigate data breaches, maintain a registry of breaches, and conduct annual cybersecurity assessments. It will also

conduct regular audits, risk assessments, and updates to security policies to address emerging threats. Regular encrypted backups will be maintained, with strict access controls for disaster recovery purposes.

4) Health Data Privacy and Privacy Standards:

The Agency will ensure privacy standards throughout the data lifecycle, guided by best practices and relevant laws. Access to health data will require authorization from the client or the data controller. Procedures for data deletion, client notification, and permanent removal of data copies are also specified.

5) Archiving of Health Information:

Data will be retained for twenty years from the last update or eight years post-confirmed death. Before archiving, identifying information will be removed to protect privacy. This regulation also provides the procedures for accessing archived data, ensuring security compliance.

6) Migration of Data:

This regulation provides that institutions must transfer legacy data to County Health Data Banks within specified periods.

7) Health Data Sharing:

Health data sharing is permitted for specified purposes, with restrictions on further transfer after the signing of formal agreements. The agency will oversee access levels and compliance with data-sharing protocols.

8) Correction of Personal Data:

Clients can request corrections to inaccurate or misleading personal data and the health data controller must correct data within seventy-two hours, with an appeals process for refusal.

9) Secondary Use of Health Data:

The use of Secondary de-identified health data for public health is allowed and the Agency will grant the rights for secondary use while ensuring compliance with legal and regulatory standards.

10) Health Data for Treatment Outside Kenya:

Clients can access and share their health records for treatment abroad, with secure access controls. Post-treatment updates to medical records will be guided by the referring healthcare provider.

11) E-Waste Management:

Health data controllers will maintain an e-waste inventory and notify the Agency before disposal. Guidelines for managing e-waste include secure data backup and compliance with disposal procedures are provided.

12) Disclosure of Personal Data, Emergencies, and Processing Sensitive Personal Data:

Procedures for requesting sensitive personal data of deceased persons are outlined and access to personal data for emergency treatment is governed by strict authentication processes.

Unauthorized disclosure of personal health data for market research is penalized. Strict identity verification and confidentiality measures are required before releasing personal health data.

REGULATION TWO: THE DIGITAL HEALTH ((USE OF E-HEALTH APPLICATIONS AND TECHNOLOGIES) REGULATIONS ,2024

The purpose of these Regulations is to operationalize section 60(b) of the Digital Health Act, No.15 of 2023 thereby improving access to the highest attainable standard of health care. These Regulations seek to provide for the use of e-health applications and technologies including digital health solutions in the provision of e-health. The Regulations require that a digital health solution to be used in the provision of healthcare services must be certified by the Digital Health Agency. The Regulations further provide that a health data controller or a health data processor using or accessing the Comprehensive Integrated Health Information System established under section 15(1)(a) of the Digital Health Act, No. 15 of 2023 shall only use a digital health solution that has been certified by the Digital Health Agency based on the Certification Framework developed and published by the Digital Health Agency every two years.

In the certification of digital health solutions, the Digital Health Agency shall—

- a. manage the certification process;
- b. ensure that health data controllers and digital health solutions comply with the Certification Framework;
- c. ensure that the Certification Framework is aligned to digital health standards and guidelines developed and published by the Cabinet Secretary for Health;
- d. disseminate the Certification Framework including the digital standards and guidelines; and
- e. set up and certify laboratory-based testing environments in collaboration with the relevant institutions for the purpose of assessing the conformity of digital health solutions with the Certification Framework.

Certification undertaken by the Digital Health Agency shall be based on several considerations including—

- a. functionality as set out in the Certification Framework including the system and data quality for each;
- b. compliance with reporting and alerts as required by the prevailing policies and guidelines in the health sector;
- c. compliance with the Information Security, Privacy and Confidentiality standards provided in the Kenya Health Data Governance Framework established under section 21(1) of the Digital Health Act; and
- d. capacity to perform information exchange and interoperability in accordance with the Interoperability Framework developed by the Cabinet Secretary for health pursuant to section 21(2)(b) of the Digital Health Act.

A digital health solution shall therefore be subjected to the functionality test and the applicable standards and guidelines for each type of digital health solution.

The certification process provided in the Regulations shall involve:

- a. self-attestation and application;
- b. document review which will require the submission of information including the the Data Protection Impact Assessment Report of the digital health solution, Policy on Security, Privacy and Confidentiality and Cyber Security Assessment Report of the digital health solution.
- c. scheduling and testing where the Digital Health Agency will communicate the results of the testing within five days from the date of the adoption of the testing report by the Board of the Digital Health Agency;
- d. certification where the Agency shall issue a certificate of compliance where the digital health solution complies with the certification framework and enter the digital health solution in the Certification Register maintained by the Digital Health Agency.
- e. re-certification and ad hoc audit where the Digital Health Agency assess compliance with certification requirements and verifies corrective actions where non-conformity may have occurred during the validity period of the certificate of compliance.
- f. review or appeals.

The Agency shall monitor compliance with the Certification Framework by digital solution providers or health data controllers and, in particular, shall:

- a. review the data quality assessments submitted by health data controllers to ensure compliance with the digital health standards and guidelines; and
- b. schedule and conduct annual audits and checks, using the tools and procedures in the Data Quality Assessment Standards, to assess adherence and compliance to Data Quality Protocols by the System and the certified digital health solutions.

The Agency shall revoke the certification of a digital health solution where:

- a. the digital solution provider or health data controller fails to adhere to the certification requirements; or
- b. a major system security breach has occurred.

A digital health solution provider or health data controller is also expected to comply with a change in the digital health standards and guidelines within six months from date of the change of the standards or guidelines to maintain the certification status. A digital health solution provider who fails to maintain the certification status shall migrate health data in the enterprise service bus in accordance with the data migration guidelines issued by the Digital Health Agency.

A digital solution provider of an existing digital health solution shall further be expected to apply for certification of his or her digital health solution within six months of the coming into force of these Regulations.

REGULATION THREE: THE DIGITAL HEALTH (ESTABLISHMENT AND IMPLEMENTATION OF THE DATA EXCHANGE) REGULATIONS, 2024

The objective of these Regulations is to give effect to section 60(d) of the Act by ensuring the safe, secure, efficient and effective sharing of information within the health sector. The Regulations therefore sets out:

- a. the administration and management of the Comprehensive Integrated Health Information System;
- b. the exchange of health information within the Comprehensive Integrated Health Information System; and
- c. the roles and responsibilities of the Digital Health Agency and other users of the Comprehensive Integrated Health Information System.

The Digital Health Agency is expected to ensure optimal functioning of the components of the System within twelve months from the coming into force of the Regulations. The Agency is also supposed to submit reports on the administration and management of the Comprehensive Integrated Health Information System to the Ministry on a quarterly basis or as may be required by the Cabinet Secretary for health.

Authorized persons from the Ministry of health and the county departments of health shall, based on the type of data required and the classification of health data in section 19 of the Digital Health Act, be given access to the System for the conduct of analysis of data for purposes of decision making, policy formulation and reporting in compliance with subnational, national, regional and global reporting requirements.

A health data controller who has been using or managing health data using a digital health solution shall, within six months upon the coming into force of these Regulations, be onboarded into the System.

The Regulations sets out the purpose of the various registries established under the Digital Health Act, 2023. The Regulations further specifies in detail the respective roles and responsibilities of the Digital Health Agency, health data controllers, health data processors, patients or clients and digital health solution providers in respect of various ICT infrastructure and shared resources provided for in section 16(a) and (e) of the Digital Health Act, No. 16 of 2023. These include the enterprise service bus, data banks, national health data dictionary, client registry, facility registry, health worker registry, the Kenya Health Enterprise Architecture, product catalogue, interoperability layer, logistics management information services, shared health records, health management information services, and finance and insurance services.

CHAPTER 6

COST-BENEFIT ANALYSIS

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

While implementing these regulations would involve substantial upfront costs, the potential long-term benefits in terms of improved healthcare delivery, cost savings, and public health outcomes could outweigh these costs. The Ministry of Health has ensured proper planning for the implementation of digital health solutions by ensuring stakeholder engagement and ongoing investment in maintenance and support to County governments to realize these benefits effectively. Additionally, rigorous evaluation and monitoring will be necessary to ensure that the system achieves its intended goals and continues to meet the evolving needs of Kenya's healthcare system.

6.1 BENEFITS AND COSTS OF THE PROPOSED REGULATIONS

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

In considering the benefits of the proposed Regulations, the key questions to be answered include:

- 1) What is the nature and extent of constraints faced by Kenyan citizens in the access to quality essential healthcare services and access to personal health information?*
- 2) To what extent is it the role of the Government to cushion the health system from emerging and re-emerging disease outbreaks and changing demographic patterns?*
- 3) To what extent do Regulations contribute to addressing the high burden of communicable conditions and non-communicable conditions?*

Kenyans will benefit greatly from the Proposed Regulations in the following ways:

a. **Improved Patient Care and Outcomes**

The Digital Health Regulations will enable seamless sharing of patient information across different healthcare providers and facilities. This enhances coordination of care, reduces medical errors, and ensures that patients receive appropriate and timely treatment. Additionally, access to comprehensive health records allows healthcare providers to make more informed clinical decisions, leading to better health outcomes for patients as well as facilitating portability of patient data.

Centralized digital platforms empower patients by providing them with access to their health information, including medical history, test results, and treatment plans. This promotes patient engagement and shared decision-making in healthcare, as patients are better equipped to participate in discussions about their care and make informed choices about treatment options.

b. Enhanced Efficiency and Cost Savings

These regulations will streamline administrative processes such as appointment scheduling, billing, information sharing, and claims processing. This reduces paperwork, minimizes duplicative efforts, and increases overall operational efficiency for healthcare providers. Moreover, interoperability eliminates the need for redundant data entry and facilitates the exchange of information between different systems, resulting in cost savings for both healthcare organizations and patients.

c. Enhance equitable Access to Quality Healthcare Services Using ICTs

Adoption of eHealth as a model of care will go a long way in mitigating health inequalities that result from differences in the social and economic conditions across geographical and political boundaries by improving access to healthcare services through technology-enabled consultation. The healthcare services and information provided through eHealth should be of good quality.

d. Promote Patient-centred Healthcare Services

Patient-centred care involves the use of point-of-care devices to attend to patients in a manner that is meaningful and valuable. This includes involving the patient in a respectful, responsive way according to their preferences, needs and values while ensuring that patient values always inform clinical decisions.

The client portal is designed in a way that, in the provision of e-health services to a client, a healthcare provider provides the client with all the information for the management of his or her health. The portal ensures the client can access their own health records where necessary and further guarantees the client's data is managed as prescribed in the law.

e. Facilitate Standardization of eHealth Solutions

Appropriate standards for eHealth hardware and software will be a requirement. Other areas that require standardization include procurement of Digital Health solutions to ensure quality, confidentiality, privacy, security, and the integrity of health data. (and compliance to reporting requirements)

f. Provide for Integration into Existing Systems

Implementation of digital health will bring together clinicians and health informatics experts to develop a unified model for the integration of digital health systems. The model will be anchored on available technologies, infrastructure, health enterprise architecture, data repositories, policies, and standard operating procedures (SOPs) already in place for smooth adoption, implementation and utilization of digital health solutions **Promote Participatory Approach**

All stakeholders to Digital Health will be involved in the design, development and implementation of interventions for the best outcomes. Public-private partnerships may be necessary to expedite the adoption of Digital Health.

g. Enhance Health Research and Development

Implementing the Digital Health Regulations shall facilitate efficient and effective sources of truth in the scope of health information. Some of this data shall be utilised for research on various aspects of health issues affecting the population that will lead to the formulation of evidence-based health solutions.

Access to comprehensive health data on a national scale enables researchers and public health authorities to conduct population-based studies, monitor disease trends, and identify emerging health threats more effectively. This facilitates evidence-based policymaking and targeted interventions to improve public health outcomes and prevent disease outbreaks.

h. Align investments from the government and implementing partners.

Implementation of comprehensive integrated digital health systems will provide implementing the government, implementing partners and healthcare providers with real-time access to accurate and up-to-date information on individual-level patient data, healthcare utilization, and service delivery. This supports strategic planning, resource allocation, and performance monitoring.

i. Stimulation of Economic Growth

The comprehensive integrated digital health systems will promote innovation and entrepreneurship in the healthcare sector by creating opportunities for the development of new technologies, software solutions, and digital health services. This stimulates economic growth, creates jobs, and attracts investment in the healthcare industry, contributing to overall economic development.

Matrix of Benefits and Costs on the Digital Health Regulations

The table below outlines an analysis of the main problems to be addressed by the proposed regulations, proposed reforms, costs and benefits.

Table 1: Benefits and Costs of the Digital Health Regulations

PROBLEM	PROPOSED REFORM	COST	BENEFIT
<p>1. System and Data Fragmentation Currently, health information in Kenya is often fragmented across various systems and facilities, leading to inefficiencies, duplication of efforts, and difficulty in accessing comprehensive patient records.</p>	<p>Maintenance of a comprehensive integrated health information system (CIHIS) that is interoperable with other health management systems.</p>	<ul style="list-style-type: none"> • Infrastructure Costs • Software Development • Data Migration Costs • System maintenance 	<ul style="list-style-type: none"> • Digital Health Regulations would centralize health data, making it easier for healthcare providers to access complete and accurate information about patients regardless of where they receive care. • Interoperability with existing HIS would streamline data exchange between different healthcare facilities, reducing duplication of efforts and improving coordination of care.
<p>2. Poor Data Quality Inaccurate or incomplete health data can compromise patient care, decision-making, and public health efforts.</p>	<p>Enforce data quality standards and validation processes to improve the accuracy, completeness, and reliability of health information.</p>	<ul style="list-style-type: none"> • Training Costs: Training healthcare professionals and IT staff on how to use the new system effectively. 	<p>Improved Data Accessibility:</p> <ul style="list-style-type: none"> • Health data is more accessible to healthcare providers, leading to better-informed decision-making and improved patient care hence better healthcare outcomes and more

			effective public health interventions.
3. Challenges in data access		•	
4. Inconsistent Data Standards (leadership & governance) The lack of standardized data formats and protocols across healthcare facilities hinders interoperability and data exchange.	Establish uniform data standards and protocols, ensuring seamless communication between different systems and improving the quality and consistency of health information.	<ul style="list-style-type: none"> • Regulatory Compliance. • Training Costs • Monitoring and Evaluation Cost. 	Uniform data standards and protocols, ensuring seamless communication between different systems and improving the quality and consistency of health information.
5. Challenges in Monitoring and Evaluation (data use) Without a comprehensive health information management system, monitoring and evaluating healthcare delivery, disease trends, and health outcomes can be challenging.	Maintenance of a comprehensive integrated Health information system (CIHIS) that is interoperable with other health management platforms.	<ul style="list-style-type: none"> • Infrastructure Costs • Software Development • Data Migration costs • Training costs 	Enhanced Public Health Monitoring: <ul style="list-style-type: none"> • The CIHIS can enable better monitoring of public health trends, disease outbreaks, and healthcare disparities, allowing for more targeted interventions and resource allocation. • Digital Health regulations provide the infrastructure and tools necessary for robust monitoring and evaluation, enabling policymakers and healthcare providers to assess the effectiveness of healthcare interventions,

			allocate resources more efficiently, and make evidence-based decisions.
<p>6. Sub-optimal System and information Security</p> <p>Many existing health information systems in Kenya lack robust cybersecurity measures, putting sensitive patient data at risk of unauthorized access, data breaches, or loss.</p>	Implementing robust cybersecurity measures to protect sensitive health information from unauthorized access or breaches that are compliant with other Data protection legislative instruments.	<ul style="list-style-type: none"> • Software Development costs. • Maintenance and Support costs. • System Evaluation and monitoring costs. • Regulatory Compliance. 	<p>Patient Empowerment</p> <ul style="list-style-type: none"> • Improved access to health information through digital systems can empower patients to take a more active role in managing their health. • Data portability.
<p>7. Limited Capacity for Research and Innovation</p> <p>The lack of access to high-quality health data hampers research and innovation in healthcare in Kenya.</p>	Provide researchers and policymakers (Data Users) with access to rich, standardized health datasets, facilitating research, epidemiological studies, and the development of innovative healthcare solutions to address the country's health challenges	<ul style="list-style-type: none"> • Infrastructure Costs • Software Development • Data Migration costs • Training costs 	<p>Enhance Research and Innovation:</p> <ul style="list-style-type: none"> • A comprehensive health information system could facilitate research and innovation in healthcare by providing researchers with access to large datasets for analysis.
8. Others	<i>There will be costs that will be borne by the vendors/owners of systems to upgrade point-of-care solutions. Counties and system implementers will also be expected to maintain end-user devices so that they are fully functioning.</i>		

CHAPTER 7

SOCIO-ECONOMIC IMPACTS

The implementation of the Digital Health Act 2023 will fully operationalize the Digital Health Agency, while the establishment of the Comprehensive Integrated Health Information System (CIHIS) can have significant socioeconomic impacts on the population.

a. Improved Healthcare Delivery

The comprehensive integrated Health Information system will enable seamless sharing of health information across healthcare providers, leading to better coordination of care, reduced medical errors, and improved patient outcomes. By facilitating timely access to patient records and medical history, healthcare professionals can make more informed treatment decisions, resulting in enhanced healthcare delivery and increased patient satisfaction.

b. Empowerment of Patients and Communities

Digital Health Regulations promote patient-centered care by empowering individuals to access and control their health information. Patients can actively participate in healthcare decision-making, monitor their health status, and engage with healthcare providers through digital platforms. Increased patient engagement fosters better health outcomes, promotes preventive care, and strengthens trust between patients and healthcare providers.

c. Public Health Surveillance and Response

The ability to track and trace HPTs as well as accurate health data will strengthen public health surveillance by providing real-time data on disease trends, outbreaks, and healthcare utilization patterns. This enables authorities to detect emerging health threats promptly, implement targeted interventions, and allocate resources effectively to mitigate the spread of diseases. Improved disease surveillance contributes to healthier populations and reduced healthcare costs associated with managing epidemics.

d. Research and Innovation

Access to comprehensive health data through the comprehensive integrated health system will facilitate medical research, epidemiological studies, and healthcare innovation. Researchers can leverage large datasets to identify trends, conduct clinical trials, and develop evidence-based interventions to address public health challenges. This fosters scientific discovery, drives medical advancements, and enhances the country's competitiveness in the global healthcare landscape.

e. Job Creation and Economic Growth

The implementation of Digital Health Solutions and the Comprehensive Integrated Health System will create opportunities for job creation and economic growth in the healthcare sector. This includes roles in data management, analytics, software development, cybersecurity, and healthcare informatics. Moreover, the adoption of digital health technologies stimulates

investment in information technology infrastructure, software development, and digital health startups, driving economic activity and innovation in related industries.

f. Enhanced Regulatory Compliance

The Digital Health Regulations establishes regulatory frameworks and standards for the collection, storage, and use of health data, ensuring compliance with data privacy and security regulations. This fosters trust among stakeholders, including patients, healthcare providers, and technology vendors, and promotes the responsible use of health information. Strengthened regulatory compliance mitigates legal risks and reputational damage associated with data breaches, thereby safeguarding the integrity of the healthcare system.

g. Cost Savings

Efficient use of health data through the Comprehensive Integrated Health System can lead to cost savings in the healthcare system. By more accurate quantification of HPT needs, reducing redundant tests on patients as they can access their health information in a portable manner, reduced medical fraud in health insurance claims and administrative overhead, healthcare providers can optimize resource allocation and minimize healthcare expenditures. Additionally, early detection and intervention enabled by comprehensive health data can prevent costly complications and hospitalizations.

Overall, the implementation of the Digital Health Act has far-reaching socio-economic benefits, including improved healthcare delivery, cost savings, enhanced public health surveillance, research opportunities, patient empowerment, job creation, economic growth, and regulatory compliance. These initiatives are essential for building resilient and efficient healthcare systems capable of addressing the evolving healthcare needs of populations in the digital age.

CHAPTER 8

CONSIDERATION OF ALTERNATIVES TO THE DIGITAL HEALTH REGULATIONS

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 regulations 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 Regulations for the Digital Health Act.

8.1 OPTION ONE: MAINTENANCE OF THE STATUS QUO

Maintaining the status quo means that no regulations are developed and, therefore, the Digital Health Act will not be fully implemented. The development of these Regulations is a requirement of the Act which seeks to address the problems and challenges that have faced the management of health information; the Act requires these Regulations for their full implementation.

The effect of non-implementation of the Regulations will include, amongst others,

- a. Fragmentation of Health Information,
- b. Data Security and Privacy Concerns,
- c. Duplication of Efforts and Resources,
- d. Limited Interoperability,
- e. Barriers to Innovation and Collaboration,
- f. Difficulty in Data Analysis and Public Health Surveillance and
- g. Inequitable Access to Healthcare Services among others.

The full implementation of the proposed regulations will address the above-highlighted challenges.

8.2 OPTION TWO: ADMINISTRATIVE MEASURES

This is a non-regulatory measure that, if applied, will depend on the goodwill of public officers to implement the provision of the new Act. Administrative measures involve the 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 a court of law.

These Regulations also seek to standardize the management of Health Data and levy payment of fees for access to the digital system and this requires the force of law for enforcement. This, therefore, necessitates the development of these regulations to streamline the implementation and achievement of UHC.

8.3 OPTION THREE: DEVELOPING THE PROPOSED DIGITAL HEALTH REGULATIONS, 2024

The development of the regulations on the Digital Health Act will facilitate the attainment of universal health care coverage. These Regulations strengthen the health system through the enhancement of service delivery, facilitate the regulation of health workforce, the management of health products and technologies and facilitate evidence-based health financing.

The Regulations are aligned with the right to the highest attainable standard of health as enshrined in the Constitution and the Health Act, Cap.241 that provides for the establishment of a comprehensive eHealth system. These Regulations seek to resolve the challenges of fragmentation of health information, data security and privacy concerns, duplication of efforts and resources, limited interoperability, barriers to innovation and collaboration, difficulty in data analysis and public health surveillance and inequitable access to healthcare services among others.

They provide a practicable approach towards health information sharing as an enabler to Universal Health Coverage.

8.4 PREFERRED OPTION

The preferred option would be the implementation of the proposed regulations to ensure that universal health coverage is effectively attained and that all Kenyans receive accessible, affordable, and quality health care while safeguarding their rights to not have the information relating to their family and private affairs unnecessarily disclosed and that every citizen has a right to access information held by the State and held by another person and required for the exercise or protection of another right (Article 35).

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 Regulations
Impact on the Public Sector	Discourages the growth of Digital Health Solutions.	Administrative measures can be implemented more quickly and adjusted more easily than formal regulations. However, this might	Ease access to health information through the provision of e-health solutions that may ease the burden of health care

		lead to inconsistent application and uncertainty among stakeholders.	promoting public trust and confidence.
Impact on the Private Sector	The private sector will largely remain unaffected.	There is no guarantee that administrative measures will address private-sector concerns.	Ease access to health information through the provision of e-health solutions that may ease the burden of healthcare.
Economic Impact	The costs associated with inefficiencies related to fragmented Health information systems, and duplication of efforts increase on costs of access to Healthcare in Kenya.	Enforcement and assurance of quality and security of Data can't be guaranteed.	The proposed measures in the Regulations will not only address the challenges but also create an enabling environment for investors.
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 health will be slowed down.	Administrative measures do not have the force of law necessary for guaranteeing human rights.	The regulations will assist in the achievement of the highest attainable standards of healthcare as well as fulfill the rights to data protection and availability of health

			information for citizens
Impact on business	Largely no impact	Lack of the force of law for full implementation of the Act.	Creates a framework for enterprises to contribute to the attainment of Digital Health solutions that will contribute to the achievement of UHC
Impact on environment	Will be generally unaffected	Will promote opportunities for investment in digital health solutions however, administrative measures do not provide mitigation of risks related to increased energy consumption and e-waste generation.	Will facilitate investment in health infrastructure leading to a better environment for all
Impact on taxes	Largely no impact	Largely no impact	Largely no impact
Impact on existing legal frameworks	The existing legal gaps will not be addressed	Regulatory concerns will remain unaddressed	Addresses all the identified gaps. Provides harmony with related legal frameworks. No further legal amendments or enactments will be required.

CHAPTER 9

PUBLIC CONSULTATIONS

9.0 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, formulates or implements public policy. This requirement is based on Article 1 of the Constitution on the sovereignty principle which vests all sovereign power on 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 accountable¹⁹.

Article 174 donates 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 principles of public service²⁰ require the involvement of the people in the process of policymaking through the provision of transparent, timely and accurate information to the public.

The Statutory Instruments Act obligates a regulation-making authority to carry out appropriate consultations before making statutory instruments, in this case, regulations, where the proposed regulations 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.

¹⁹ Article 10 of the Constitution

²⁰ Article 232 of the Constitution

The Act also states that the persons to be consulted should be notified either directly or by advertisement through representative organizations. It further notes that these people shall also be invited to make submissions on 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 THE PROCESS OF PUBLIC PARTICIPATION

According to Section 5 of the Statutory Instruments Act, the Ministry of Health identified specific stakeholders with whom it engaged in a consultative process. These include the professional and specialist institutions and individuals who will be directly or indirectly affected by the Regulations.

9.2 STAKEHOLDER MAPPING

The stakeholders identified for purposes of developing the Regulations included:

1. Ministry of Health
2. Counties
3. CSOs and Patient groups
4. Other MDAs (National Treasury, MOICDE, ODPC, KENAS)
5. Professional Associations
6. Academic, Research, and Training Institutions
7. Regulatory Bodies
8. Digital Health Implementers and Vendors
9. Private Health Providers
10. Health Insurance Providers
11. Health Products and Technologies suppliers
12. Bilateral/Multilateral partners

9.3 PUBLIC CONSULTATION APPROACH AND METHODOLOGY

The following approaches and methodologies will be applied during the consultation process:

- (a) Physical meetings;
- (b) Letters;
- (c) Virtual meetings;
- (d) Emails;
- (e) Ministry of Health website;
- (f) Publication in the local dailies and;
- (g) Publication in the Gazette Notice.

CHAPTER 10

IMPLEMENTATION OF THE REGULATIONS

10.0 COMPLIANCE AND IMPLEMENTATION

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

The implementation and enforcement of the Regulations will be undertaken through the existing institutional framework at the National level (Ministry of Health) and the County level (County Governments).

10.1.1 The Role of National Government

The Ministry of Health plays a pivotal role in the implementation of these Regulations by defining standards that are used. This is a collaborative process that involves all relevant stakeholders. In addition, the MoH's oversight of the Digital Health Agency (DHA) ensures the enforcement of these standards, guaranteeing that certified solutions meet the highest quality benchmarks.

10.1.2 The Role of Counties

The County Governments, through their departments of Health, are essential in the Digital Health implementation process serving as both users of digital health systems and overseers of health service delivery in these devolved units.

10.2 CONCLUSION

These Regulations play a crucial role in promoting the adoption and use of technology to improve healthcare delivery which is key for the implementation of Universal Health Coverage. They offer socio-economic, environmental, and legal benefits which include ease of accessing medical care, patient data portability, and patient data protection, among other benefits that enhance patient outcomes, and advance public health goals in Kenya.

The Regulations also provide a framework for ensuring that the people of Kenya enjoy rights to the highest attainable standard of health as well as the right to privacy, which are enshrined in the Constitution. These Regulations under the Digital Health Act are extremely necessary.

10.3 RECOMMENDATION

In view of the above conclusion, it is recommended the adoption of the proposed;

1. The Digital Health (Use of E-Health Applications and Technologies) Regulations, 2024) Regulations;
2. The Digital Health (Health Information Management) Regulations, 2024; and The Digital Health (Data Exchange) Regulations, 2024.