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THE STANDING COMMITTEE ON HEALTH

REPORT ON THE DIGITAL HEALTH BILL, 2023  
(NATIONAL ASSEMBLY BILLS NO. 57 OF 2023)

PAPERS LAID	
DATE	11/10/2023
TABLED BY	Sen. Esther Okenyuni MP
COMMITTEE	Health
CLERK AT THE TABLE	Abdirahman

Clerk's Chambers,  
First Floor,  
Parliament Buildings,  
NAIROBI.

OCTOBER, 2023

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## ABBREVIATIONS AND ACRONYMS

<b>AKI</b>	-	Association of Kenya Insurers
<b>CHAK</b>	-	Christian Health Association of Kenya
<b>CoG</b>	-	Council of Governors
<b>COTU</b>	-	Central Organisation of Trade Unions
<b>FKE</b>	-	Federation of Kenya Employers
<b>IRA</b>	-	Insurance Regulatory Authority
<b>KHF</b>	-	Kenya Healthcare Federation
<b>MOH</b>	-	Ministry of Health
<b>NHIF</b>	-	National Hospital Insurance Fund
<b>RUPHA</b>	-	Rural Private Hospitals Association
<b>SHA</b>	-	Social Health Authority

## PRELIMINARIES

### A. Establishment and Mandate of the Standing Committee on Health

The Standing Committee on Health is established pursuant to standing order 228 (3) and the Fourth Schedule of the Senate Standing Orders and is mandated to *consider all matters relating to medical services, public health and sanitation.*

### B. Membership of the Committee

The Committee is comprised of the following Members:

- |    |   |   |                    |
|----|---|---|--------------------|
| 1. | <b>Sen. Jackson Kiplagat Mandago, EGH, MP</b> | - | <b>Chairperson</b> |
| 2. | <b>Sen. Mariam Sheikh Omar, MP</b>            | - | <b>Vice</b>        |
|    | <b>Chairperson</b>                            |   |                    |
| 3. | Sen. Erick Okong'o Mogeni, SC, M              |   |                    |
| 4. | Sen. Ledama Olekina, MP                       |   |                    |
| 5. | Sen. Abdul Mohammed Haji, MP                  |   |                    |
| 6. | Sen. Hamida Kibwana, MP                       |   |                    |
| 7. | Sen. Joseph Nyutu Ngugi, MP                   |   |                    |
| 8. | Sen. Raphael Chimera Mwinzagu, MP             |   |                    |
| 9. | Sen. Esther Anyieni Okenyuri, MP              |   |                    |

### C. Functions of the Committee

Pursuant to Standing Order 228(3), the Committee functions to –

1. Investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration and operations of its assigned ministries and departments;
2. Study the programme and policy objectives of its assigned ministries and departments, and the effectiveness of the implementation thereof;
3. Study and review all legislation referred to it;
4. Study, assess and analyze the success of the ministries and departments assigned to it as measured by the results obtained as compared with their stated objectives;
5. Consider the Budget Policy Statement in line with Committee's mandate;
6. Report on all appointments where the Constitution or any law requires the Senate to approve;
7. Make reports and recommendations to the Senate as often as possible, including recommendations of proposed legislation;
8. Consider reports of Commissions and Independent Offices submitted to the Senate pursuant to the provisions of Article 254 of the Constitution;

9. Examine any statements raised by Senators on a matter within its mandate; and
10. Follow up and report on the status of implementation of resolution within their mandate.

#### **D. Government Agencies and Departments**

In exercising its mandate, the Committee oversees the County Governments, the Ministry of Health and its various Semi-Autonomous Government Agencies (SAGAs).

## FOREWORD BY THE CHAIRPERSON

**Hon. Speaker,**

The Digital Health Bill (National Assembly Bills No. 57 of 2023) was published *vide* Kenya Gazette Supplement No. 163 of 11<sup>th</sup> September, 2023.

The Bill seeks to provide a framework for the provision of digital health services; to establish a comprehensive integrated digital health information system; and, to provide for data governance and protection of personal health information in service delivery through digital health interventions, e-waste disposal and health tourism.

It was introduced in the National Assembly by way of First Reading on Thursday, 14<sup>th</sup> September, 2023. The Bill was considered by the National Assembly and passed with amendments on Thursday, 27<sup>th</sup> September, 2023.

Pursuant to Article 110(4) of the Constitution, the Bill was referred to the Senate where it was introduced by way of First Reading on Tuesday, 3<sup>rd</sup> October, 2023. It thereafter stood committed to the Standing Committee on Health pursuant to standing order 145.

In compliance with the provisions of Article 118 of the Constitution and Standing Order 145 (5) of the Senate Standing Orders, the Committee proceeded to undertake public participation on the Bill.

In this regard, the Committee published an advertisement in the Daily Nation and Standard newspapers on Wednesday, 4<sup>th</sup> October, 2023, inviting members of the public to submit written memoranda to the Committee on the Bill.

Additionally, the Committee sent invitations to key stakeholders inviting them to submit their comments on the Bill as follows -

- a) Government Departments/Agencies
  - Ministry of Health (MoH)
  - Council of Governors (COG)
  - National Health Insurance Fund (NHIF)
  - Insurance Regulatory Authority (IRA)
- b) Trade Unions
  - Central Organisation of Trade Unions (COTU)
- c) Private Sector
  - Federation of Kenya Employers (FKE)
  - Kenya Healthcare Federation (KHF)
  - Christian Health Association of Kenya (CHAK)
  - Rural Private Health Association (RUPHA)
  - Association of Kenya Insurers (AKI)

Further, following the call for submissions, the Committee received written memoranda from various stakeholders, namely: Ministry of Health (MoH); Council of Governors (COG); National Health Insurance Fund (NHIF); Insurance Regulatory Authority (IRA); Central Organisation of Trade Unions (COTU); Federation of Kenya Employers (FKE); Kenya Healthcare Federation (KHF); Christian Health Association of Kenya (CHAK); Rural Private Health Association (RUPHA); Association of Kenya Insurers (AKI); Kenya Union of Clinical Officers (KUCO); Pharmaceutical Society of Kenya (PSK); Confraternity of Patients Kenya; International Budget Partnership - Kenya (IBP-Kenya); Kenya Faith-Based Health Services Consortium; The Actuarial Society of Kenya (TASK); Association of Kenya Medical Laboratory Scientific Officers (AKMLSO); Health NGOs Network (HENNET); International Commission of Jurists (ICJ); Kenya Dental Association (KDA); Health Records and Information Management Professionals (comprising the Health Records and Information Managers Board and the Association of Medical Records Officers); Civil Society Organisations (comprising the Kenya AIDS NGOs Consortium (KANCO), Amnesty International Kenya, People's Health Movement (PHM) and the Institute of Public Finance (IPF)), Tech Hive Advisory Africa, and Helium Health Limited.

The Committee proceeded to consider the Bill at the length and held extensive discussions thereon including consultations with key stakeholders. This Report is therefore the product of extensive consultations that have taken place to ensure that we have a good law in place that will stand the test of time.

**Hon. Speaker,**

May I take this opportunity to commend the Members of the Committee for their devotion and commitment to duty, which made the consideration of the Bill successful.

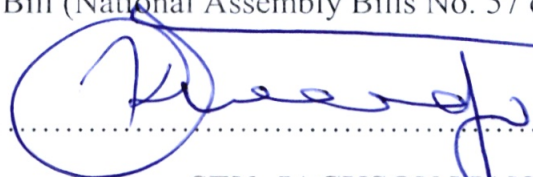
I also wish to thank the Offices of the Speaker and the Clerk of the Senate for the support extended to the Committee in undertaking this important assignment.

Lastly, I wish to thank the stakeholders who submitted written memoranda which greatly aided the Committee in considering the Bill.

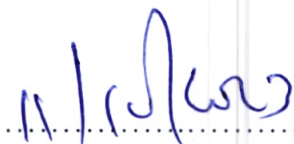
**Hon. Speaker,**

It is now my pleasant duty, pursuant to standing order 148(1) of the Senate Standing Orders, to present the Report of the Standing Committee on Health on The Digital Health Bill (National Assembly Bills No. 57 of 2023)

Signed .....



Date.....

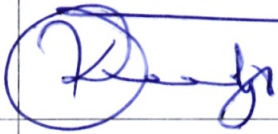






**SEN. JACKSON MANDAGO, EGH, M.P.**

**CHAIRPERSON, STANDING COMMITTEE ON HEALTH**

**ADOPTION OF THE REPORT OF THE STANDING COMMITTEE ON HEALTH ON THE Digital Health Bill (National Assembly Bills No. 57 of 2023)**

We, the undersigned Members of the Senate Standing Committee on Health, do hereby append our signatures to adopt this Report –

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>
1.	Sen. Jackson Kiplagat Mandago, EGH, MP	Chairperson	
2.	Sen. Mariam Sheikh Omar, MP	Vice-Chairperson	
3.	Sen. Erick Okong'o Mogeni, SC, M	Member	
4.	Sen. Ledama Olekina, MP	Member	
5.	Sen. Abdul Mohammed Haji, MP	Member	
6.	Sen. Hamida Kibwana, MP	Member	
7.	Sen. Joseph Nyutu Ngugi, MP	Member	
8.	Sen. Raphael Chimera Mwinzagu, MP	Member	
9.	Sen. Esther Anyieni Okenyuri, MP	Member	

## CHAPTER ONE

### INTRODUCTION

#### A. Introduction

- 1) The Digital Health Bill (National Assembly Bills No. 57 of 2023) was published *vide* Kenya Gazette Supplement No. 164 of 11<sup>th</sup> September, 2023.
- 2) The Bill seeks to provide a framework for the provision of digital health services; to establish a comprehensive integrated digital health information system; and, to provide for data governance and protection of personal health information in service delivery through digital health interventions, e-waste disposal and health tourism.
- 3) The Bill was introduced in the National Assembly by way of First Reading on Thursday, 14<sup>th</sup> September, 2023. The Bill was considered by the National Assembly and passed with amendments on Thursday, 27<sup>th</sup> September, 2023. A copy of the Bill as passed by the National Assembly and referred to the Senate has been attached to this report as *Annex 2*.
- 4) Pursuant to Article 110(4) of the Constitution, the Bill was referred to the Senate where it was introduced by way of First Reading on Tuesday, 19<sup>th</sup> September, 2023, and thereafter stood committed to the Standing Committee on Health pursuant to standing order 145.
- 5) In compliance with the provisions of Article 118 of the Constitution and Standing Order 145 (5) of the Senate Standing Orders, the Committee proceeded to undertake public participation on the Bill.
- 6) In this regard, the Committee published an advertisement in the Daily Nation and Standard newspapers on Wednesday, 4<sup>th</sup> October, 2023, inviting members of the public to submit written memoranda to the Committee on the Bill. A copy of the advert as published has been attached to this report as *Annex 3*.
- 7) In addition, the Committee sent invitations to targeted stakeholders including government departments and agencies, private sector, Non-Governmental Organizations/development partners and faith-based organizations. Copies of the letters of invitation to the various stakeholders have been attached to this report under *Annex 4*.

#### B. Background

- 8) Article 43 of the Constitution of Kenya guarantees all citizens the right to the highest attainable standard of health. This includes access to reproductive health care, and emergency medical treatment.

- 9) Section 104 of the Health Act, 2017 mandates the Cabinet Secretary for Health to within, three years from 7<sup>th</sup> July, 2017, ensure the enactment of an e-health legislation that provides for, among other things: the administration of health information banks including interoperability framework, data interchange and security; the collection and use of personal health information; the management of disclosure of personal health information; the protection of privacy; business continuity, emergency and disaster preparedness; health service delivery through M-health, E-learning and telemedicine; E-waste disposal; and health tourism.
- 10) The Government of Kenya has committed to accelerating the attainment of Universal Health Coverage (UHC) as a key agenda for enhancing socio-economic development: The digital transformation of the health sector is expected to leverage on IT to drive responsiveness, efficiency, transparency and seamless provision of health services as a key enabler for the attainment of UHC.
- 11) The Digital Health Bill further presents a vital response to a rapidly evolving landscape of healthcare in the digital era, where digital technologies are increasingly shaping the way healthcare services are delivered and managed.
- 12) It is grounded on the urgent need to establish a robust legal framework that aligns with the digital transformation of healthcare systems, and aims to: set out clear guidelines and regulations for the adoption, management, and safeguarding of digital health information; enhance patient-centered care; streamline healthcare operations; and, leverage on real-time data to draw timely insights to improve health outcomes.

### **C. Objects of the Bill**

- 13) The principal object of the Bill is to provide a framework for the provision of digital health services, to establish the Digital Health Agency, to establish a comprehensive integrated digital health information system and to provide for data governance and protection of personal health information in service delivery through digital health interventions, e-waste disposal and health tourism.

### **D. Overview of the Bill**

- 14) **PART I (clauses 1-4)** of the Bill contains preliminary provisions that include: the short title; interpretation; objects of the act; and, the guiding principles of the Bill.
- 15) **PART II (clauses 5-14)** establishes the **Digital Health Agency** and provides for the Board, its functions, powers, qualification of members and appointment of the Chief Executive Officer among others.
- 16) **Clause 5** establishes the Digital Health Agency and provides that it would be a body corporate with perpetual succession and a common seal.
- 17) **Clause 6** provides for the **functions of the Digital Health Agency** to include —
  - a) To develop, operationalize and maintain the Comprehensive Integrated Health Information System;

- b) establish registries to create single source of truth in respect of clients, health facilities, healthcare providers, health products and technologies;
- c) establish a system of shareable and portable personal health records, based on best practices and standards;
- d) facilitate collection and analysis of data to inform policy and research in the health sector;
- e) develop and implement the infrastructure for health data exchange of health information in a secured manner;
- f) maintain, in collaboration with the counties and other statutory authorities, the technological infrastructure necessary for the core digital health services;
- g) support the development and implementation of standards for enhanced interoperability; and
- h) undertake resource mobilization for implementation of health digitization in the country.

18) **Clause 7** provides that the **Board of Directors** (established under clause 8) will be responsible for the management and administration of the Digital Health Agency.

19) **Clause 8** outlines the **composition of the Board of Directors** of the Digital Health Agency and states that it will consist of —

- a) a non-executive chairperson who shall be competitively recruited and appointed by the President;
- b) the Principal Secretary responsible for Health or a representative designated in writing;
- c) the Principal Secretary responsible for National Treasury or a representative designated in writing;
- d) the Principal Secretary responsible for Information, Communication and Technology or a representative designated in writing;
- e) the Data Commissioner or a representative designated in writing;
- f) one person nominated by the Council of County Governors;
- g) 'one person representing the private sector appointed by the Cabinet Secretary;
- h) two persons, not being public officers, appointed by the Cabinet Secretary by virtue of their knowledge and experience in digital health; and
- i) the Chief Executive Officer, who shall be an *ex-officio* member of the Board.

- 20) **Clause 9** provides that the Board of Directors of the Digital Health Agency will adhere to the procedure set out in the Schedule and otherwise regulate its own procedures.
- 21) **Clause 10** empowers the Board of Directors of the Digital Health Agency to form such committees as it deems necessary to perform its functions.
- 22) **Clause 11** mandates the Board of Directors of the Digital Health Agency to recruit and appoint a suitably qualified Chief Executive Officer on terms determined by the Board in consultation with the Salaries and Remuneration Commission.
- 23) **Clause 12** provides that a person qualifies for appointment as a Chief Executive Officer if they have a Master's Degree, have at least ten years' knowledge and experience in a relevant field, have served in a management level for at least five years, have not been convicted of an offense and meet the requirements of Chapter Six of the Constitution.
- 24) It further provides that the Chief Executive Officer would be the accounting officer of the Digital Health Agency and will be responsible for the day to day management of the affairs and staff of the Board. It further provides that the Chief Executive Officer will hold office for three years and only be eligible for reappointment once for a further three years.
- 25) **Clause 13** provides for a Corporation Secretary, to be competitively recruited and appointed by the Board of Directors of the Digital Health Agency on terms to be determined by the Board in consultation with the Salaries and Remuneration Commission.
- 26) It further provides that a person qualifies for appointment as a Corporation Secretary if they have a degree in Law, are an Advocate of the High Court, have at least five years' experience as a corporation secretary or a similar governance role, are in good standing with the Institute of Certified Secretaries of Kenya, and, meet the requirements of Chapter Six of the Constitution. It also provides that the Corporation Secretary will be the secretary to the Board.
- 27) **Clause 14** empowers the Board of Directors of the Digital Health Agency to appoint such staff as it may deem necessary for the discharge of the functions of the Agency on terms to be determined by the Board on the advice of the Salaries and Remuneration Commission.
- 28) **Part III (clauses 15-18)** provides for the **establishment and administration of the Comprehensive Integrated Health Information System:**
- 29) **Clause 15** establishes a comprehensive integrated health information system to be administered by the Digital Health Agency. It mandates the Agency, in consultation with the Cabinet Secretary for Health, to establish a framework for the administration and management of the system, and provides that the system will operate as a point of collection, collation, analysis, reporting, storage, usage,

sharing, retrieval or archival of data related to the state of physical or mental health of the data subjects.

- 30) **Clause 16** sets out the **components of the comprehensive integrated health information system**. It provides that the system will comprise of: an information and communication technology environment which consists of the underlying infrastructure, enterprise service bus, standards, data banks, data exchange, governance, actors and applications, internet enabled environment and other related components; data collection, collation, analysis, reporting, storage, usage, sharing, retrieval, or archival; applications, infrastructure, tools and best practices; data quality assurance and audit; and shared or common resources including the national health data dictionary, client registry, facility registry, health worker registry, the Kenya Health Enterprise Architecture, product catalog, interoperability layer, logistics management information services, shared health records, health management information services, and finance and insurance services.
- 31) **Clause 17** on the other hand provides that the **main objectives of the comprehensive integrated health information system** will 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;
  - d) facilitate data processing and use;
  - e) safeguard the privacy, confidentiality and security of health data;
  - f) serve the health sector and facilitate the realization of universal health coverage;
  - g) ensure standardization of health data management; and
  - h) facilitate the tracking and tracing of health products and technologies.
- 32) **Clause 18** mandates the Digital Health Agency to adopt relevant internationally accepted standards, procedures, technical details, best practices, and formalities for effective implementation of the system. It further stipulates that the processes and technical aspects of the comprehensive integrated health information system will be guided by confidentiality, security and privacy; scalability and interoperability; accuracy, responsiveness and reliability; efficiency and effectiveness; redundancy; transparency; simplicity and accessibility; and consistency in use.
- 33) **Part IV (clauses 19-23)** provides for **health data governance** including the classification of health data and the establishment of a health data governance framework by the Cabinet Secretary in consultation with the Director-General.
- 34) **Clause 19** makes provision for **classification of health data**. It stipulates that health data will be classified into: sensitive personal level health data; de-identified,

pseudo-anonymized or anonymized individual-level health data; administrative data; aggregate health data; medical equipment data; and research for health data.

- 35) **Clause 20** makes provision for **governing principles of health data**. It provides that health data will be governed by the need to: improve client health; safeguard individuals and communities against harm and violations; data security throughout the entire data life-cycle; equity and accountability; privacy and confidentiality; and accuracy and reliability.
- 36) **Clause 21** on the other hand mandates the Cabinet Secretary for Health, in consultation with the Director-General of Health, to **establish a health data governance network**. It specifically mandates the Cabinet Secretary to develop guidelines to promote effective use of legacy data, establish standards for integration, ensure regular update and availability of the national health data dictionary for utilization within the system, interoperability and exchange of health data, establish standards for and conduct routine data quality checks in the system, ensure the security and accountability of data for the system while promoting appropriate data use and sharing, require all health data controllers and processors to report designated health data in accordance with ministry of health in the approved and prescribed formats and platforms.
- 37) **Clause 22** stipulates that the Digital Health Agency would be the **custodian of all health data** in Kenya.
- 38) **Clause 23** mandates the Cabinet Secretary for Health to ensure that health data is used for public good and further mandates the Digital Health Agency provide health data to the Cabinet Secretary for relevant action.
- 39) **Part V (clauses 24-39)** provides for **confidentiality, privacy and security of data** including security, privacy and disclosure of data in the system; retention and disposal of data in the system; establishment of health data banks; and the use of sensitive personal data; responsibilities of health controller of a health data bank.
- 40) **Clause 24 mandates the Cabinet Secretary for Health to be responsible** for the confidentiality, privacy and security of all sensitive personal data held in the comprehensive integrated health information system. It further mandates the Cabinet Secretary to establish the security measures in the system to protect sensitive personal data. It also prohibits the disclosure of sensitive personal data held in the system to a third party unless—
  - a) the data subject is unable to give informed consent and such consent is given by a person authorised by the data subject in writing;
  - b) the disclosure has been authorised by the implementation of written law or the enforcement of a court order;
  - c) a health service without informed consent as authorised by written law or court order is being provided;

- d) the data subject is being treated in an emergency situation;
  - e) failure to treat the data subject, or a group of people which includes the data subject, would result in a serious risk to public health; or
  - f) a delay in providing a health service to the data subject may result in death or irreversible damage to the health of the data subject and the data subject has not expressly, by implication or by conduct refused that service.
- 41) **Clause 25** stipulates that **data held in the system be maintained for at least twenty years**. It however proceeds to state that the data may be maintained for a period exceeding twenty years where it is required or authorized by law, authorized by the data subject, reasonably necessary for a lawful purpose or for historical, statistical or research purposes.
- 42) **Clause 26** makes provision for the **establishment of health data banks**. It mandates the Cabinet Secretary for Health to establish a national health data bank and designate county health data banks, store the health data submitted to the system in the national health data bank and establish seamless integration and interoperability of the national health data bank with other relevant databases.
- 43) Clause 26 further mandates all county executive committee members for health to establish county health data banks, store the health data submitted to the system in the county health data bank and establish seamless integration and interoperability of the county health data bank with other relevant databases and data banks. It also requires all data controllers to transmit health data containing sensitive personal data to the national health information data bank and county health information data bank in a secure and encrypted form and maintain records of the health data containing sensitive personal data so transmitted.
- 44) **Clause 27** makes provision for the **use of sensitive personal data**. It stipulates that health data contained in a health data bank be applied—
- a) to identify a person who needs or is receiving a health service;
  - b) to provide health services or facilitate care or treatment;
  - c) to identify a health service provider who is providing a health service;
  - d) to identify a person offering health insurance;
  - e) to assess and address public health needs;
  - f) to conduct disease surveillance, research and innovation;
  - g) to engage in health system planning, management, evaluation or improvement;
  - h) to assess the safety and effectiveness of health services; and

- i) for continuous enhancement of the comprehensive integrated health information system.
- 45) **Clause 28** on the other hand **mandates the data controllers of health data banks** to take reasonable measures to ensure that no agent or the data controller or processor collects, uses, discloses, retains or disposes of sensitive personal data unless it is in accordance with the law; and to remain responsible for any sensitive personal data that is collected, used, disclosed, retained or disposed of by the data controller's or processor's agents, regardless of whether or not the collection, use, disclosure, retention or disposal was carried out in accordance with the provisions of the Bill or other law.
- 46) **Clause 29** mandates persons authorized by the data controller to enter sensitive personal data into the system to ensure compliance with the relevant law when disclosing sensitive personal data about deceased persons.
- 47) **Clause 30** makes provision for **disclosure of sensitive personal data of deceased persons**. It empowers data controllers to disclose sensitive personal data about deceased persons when identifying the person, informing a person to whom it is reasonable to inform in the circumstances or investigating the cause of death
- 48) **Clause 31** requires that they obtain **consent to process sensitive personal data** except where a health service is being provided for public health in accordance with the Public Health Act and in compliance with any other statutory requirements. It further requires health care providers, when processing personal data, to ensure confidentiality of the information of the client, provide prompt and accurate data necessary for treatment of the patient and comply with the duty to notify the data subject in accordance with the Data Protection Act, 2019. It also empowers a data subject who has issued consent to the use or disclosure of personal data to withdraw their consent at any time by notifying the respective health care provider.
- 49) **Clause 32** makes provision for **classification of health data**. It stipulates that where a data subject is a minor or does not have the capacity to issue informed written consent, the parent, an appointed guardian or next friend of the data subject acts on behalf of, and in the best interest of, the data subject in accordance with the law.
- 50) **Clause 33** mandates data controllers to **protect sensitive personal data** and adopt reasonable administrative, technical and physical safeguards to ensure the **privacy, confidentiality, security, accuracy and integrity of the data**. It further mandates data controllers to establish controls that govern persons who may use sensitive personal data and stipulates that such data shall not be used unless the identity of the person seeking to use the information is verified, the data processor is authorized to use it and the proposed use is authorized under the Bill.
- 51) **Clause 34** on the other hand mandates the Cabinet Secretary for Health to develop **regulations for the disposal of sensitive personal data**.
- 52) **Clause 35** makes provision for breach of health data. It makes it an offense when a person, in relation to health data, tampers with the data, abuses a privilege, discloses

inauthentic access to the data, improperly disposes of unnecessary but sensitive data, loses the data, steals the data, or shares sensitive personal data to an unauthorized party. The **penalty** for the **offense** is a fine not exceeding one million shillings or imprisonment for a maximum of fifteen years, or both such fine and imprisonment. However, where the offense is with respect to sensitive personal data, the penalty will be a fine not exceeding three million shillings or imprisonment for a maximum of ten years, or both such fine and imprisonment.

- 53) **Clause 36** makes provision for **health data portability**. It empowers any person, upon application in writing to the relevant health facility, to examine and receive a copy of their personal health information maintained by a data controller.
- 54) **Clause 37** on the other hand empowers the person in charge of a health data bank to refuse to grant **access to a third party** a person's sensitive data or health information if it is reasonable to believe that access is restricted by a court process, order or judgment, another law prohibits disclosure, the information was collected or created in the course of an inspection, investigation or similar procedure not yet concluded, access may lead to the identification of a person who provided information in the record to the custodian in circumstances in which confidentiality was expected or access may result in the release of another person's personal health data.
- 55) **Clause 38** makes provision for **precautions on release of sensitive personal health data**. It mandates all health data banks and health data controllers, before releasing any personal health data, to be satisfied as to the identity of the person making the request and take reasonable steps to ensure that the information is received only by the intended person. It also prohibits health data controllers from disclosing, for the purpose of market research, personal health information contained in a health data information bank.
- 56) **Clause 39** makes provision for the **right to rectification or erasure of data**. It allows a health data bank or a health provider, upon request by the data subject, to—
- a) inaccurate, outdated, incomplete or misleading; or
  - b) erase or destroy, without undue delay, personal data that the health data bank or health provider is no longer authorized to retain, or personal data which is irrelevant, excessive or obtained unlawfully.
- 57) **Part VI (Clauses 40-44)** of the Bill provides for **e-health service delivery** to be delivered through telemedicine, electronic health records, m-health, e-learning, telehealth and any other recognized e-health service.
- 58) **Clause 40** provides that e-Health would be a **recognized model of health service delivery** and that stipulates that **e-Health services** would be complementary to existing healthcare service delivery modalities.

- 59) **Clause 41** provides that e-Health services would be provided through telemedicine, electronic health records, m-health, e-learning, telehealth and any other recognized e-health service. It also mandates the Cabinet Secretary for Health to develop standards and guidelines for an e-Health platform. It further stipulates that an entity providing e-health services shall be—
- a) a healthcare provider holding a valid licence issued by a relevant regulatory body;
  - b) a healthcare provider holding a valid licence from an equivalent regulatory authority outside Kenya but recognized by the local regulatory authority;
  - c) a health facility licensed to offer e- health services by the relevant regulatory body; or
  - d) for foreign facilities, be licensed by an equivalent regulatory authority recognized in Kenya.
- 60) **Clause 42** on the other hand makes provision for the **principles and objectives of e-Health**. It provides that e-Health service will be an integral part of health service delivery to benefit people in a manner that is ethical, safe, secure, reliable, equitable and sustainable.
- 61) It further lists the objectives of e-Health as to promote patient-centered health care services, ensure equitable access to quality health care services using Information and Communication Technology, promote the integration of e-health into the healthcare system, facilitate the integration of e-health solutions and promote the use of e-health solutions.
- 62) **Clause 43** stipulates that in the provision of e-health services to a client, a healthcare provider will be required to provide the client with all the information for the management of their health, ensure the client can access their own health records where necessary, ensure the client's data is managed as prescribed by law, ensure the highest possible quality of care is delivered, ensure that the agents of the e-health service provider adhere to the provisions of the Bill once enacted, ensure the platform used is interoperable with the comprehensive integrated health information system and that qualified consent is obtained. It also states that the use of e-health service platforms to share the information of a patient for consultation and training shall adhere to the standards prescribed by law.
- 63) **Clause 44** provides that when delivering e-health services, e-health service providers will be responsible for meeting their reporting obligations in accordance with the provisions of the Bill once enacted.
- 64) **PART VII (Clause 45)** of the Bill provides for e-waste management through development of guidelines for the safe handling and disposal of all health sector related e-waste material.

- 65) **Clause 45** makes provision for e-waste management. It mandates the Cabinet Secretary for Health to develop guidelines, in consultation with county governments and relevant lead agencies, for the safe handling and disposal of all health sector related e-waste material and to develop, in consultation with relevant stakeholders, an e-waste management system for the health sector.
- 66) It also provides that the e-waste management system shall comprise an appropriate mechanism for segregation of e-waste at source, collection, transportation and processing; promote reuse and lifetime extension; promote activities aimed at resource recovery and recycling of e-waste materials into useful products; embrace the best available technologies and practices in e-waste management; and promote sustainable models for e-waste management through public-private partnerships.
- 67) **Part VIII (Clauses 46 and 47)** of the Bill deals with health tourism and it provides that the Cabinet Secretary shall take all necessary measures to safeguard the transfer of medical records to and from facilities outside Kenya.
- 68) **Clause 46** makes provision for the **development of guidelines on health tourism**. It mandates the Cabinet Secretary for Health to take all necessary measures to safeguard the transfer of a client's medical records to and from facilities outside Kenya. It further mandates the Cabinet Secretary to develop guidelines on health tourism in consultation with county governments and relevant lead agencies. It further mandates a data controller in transfers outside Kenya of biological specimens, health images, human tissues and organs of a Kenyan citizen to ensure confidentiality of personal health information.
- 69) **Clause 47** makes provision for **disclosure of sensitive personal data to organizations outside Kenya**. It provides that personal health information may only be shared to a person outside Kenya for the purposes of health tourism
- 70) **Part IX (clauses 48 - 54)** of the Bill provides for the **financial provisions** including sources of funds for the Agency; the financial year; annual estimates; accounts and audit; annual report and bank accounts.
- 71) **Clause 48** provides that the **funds of the Digital Health Agency** would consist of monies appropriated by the National Assembly, monies or assets that accrue to the Agency in the course of the exercise of its powers or in the performance of its functions, such levy fees for services rendered by the Agency, monies from any other source provided, donated, lent or given as a grant to the Agency and any other funds designated for or accruing to the Agency by operation of law. It also provides that funds of the Agency shall be utilized for expenditure incurred, administrative expenses or any other purpose necessary for the discharge of the functions of the Agency.
- 72) **Clause 49** provides that the financial year of the Digital Health Agency will be the period of twelve months ending on thirtieth June in each year.
- 73) **Clause 50** on the other hand makes provision for the **annual estimates** of the Digital Health Agency. It mandates the Chief Executive Officer of the Agency to cause to

be prepared estimates of the revenue and expenditure of the Agency before the commencement of each financial year. It requires the annual estimates to be approved by the Board and be submitted by the Chief Executive Officer for tabling in the National Assembly. It further prohibits incurring of expenditure for purposes of the Agency otherwise than in accordance with the approved annual estimates tables before the National Assembly.

- 74) **Clause 51** makes provision for **accounts and audit**. It mandates the Board of Directors of the Digital Health Agency to cause to be kept all proper audit books and records of accounts of the income, expenditure, assets and liabilities of the Agency and require the accounts of the Agency be audited and reported upon in accordance with the Public Finance Management Act, 2012 and the Public Audit Act, 2015.
- 75) **Clause 52** mandates the Chief Executive Officer of the Digital Health Agency to prepare an **annual report** on the activities of the Agency at the end of each financial year and that the report be submitted for tabling in the National Assembly not later than one month after the submission of the Auditor-General's report.
- 76) **Clause 53** empowers the Chief Executive Officer of the Digital Health Agency to, in accordance with the law relating to the management of public finance, **open bank accounts** on behalf of the Agency with the approval of the Board of Directors of the Agency and the National Treasury and be responsible for the proper management of the finances of the Agency.
- 77) **Clause 54** makes provision for **investment of funds of the Digital Health Agency**. It stipulates that all monies in the Agency not immediately required be invested in such investment in a reputable bank on the advice of the Central Bank of Kenya, being an investment in which trust funds, or part thereof, are authorized by law to be invested; and in government securities as may be approved by the National Treasury. It further mandates all investments made be held in the name of the Agency.
- 78) **Part X (clauses 55 - 62)** of the Bill provides for the **miscellaneous provisions** including protection from liability; conflict of interest; confidentiality; offenses; regulations and compliance with the Data Protection Act, 2019.
- 79) **Clause 55** makes provision for **protection from personal liability**. It provides that nothing done by a member Board of Directors, employee or agent of the Digital Health Agency would, if done in good faith and for executing provisions of the Bill once enacted, render the member, employee or agent liable for any action, claim or demand arising from the action.
- 80) **Clause 56** on the other hand makes provision for **conflict of interest**. It requires a member of the Board of Directors of the Digital Health Agency who has a direct or indirect personal interest in a matter being considered by the Board to, as soon as reasonably practicable after the relevant facts concerning the matter have come to their knowledge, disclose the nature of such interest, failure to which that member commits an offense. It further requires the member of the Board with such interest

to recuse themselves from proceedings before the Board in which they have apparent or perceived conflict of interest.

- 81) **Clause 57** prohibits members of the Board of Directors of the Digital Health Agency and staff of the Agency from, without the consent of the Board, publishing or disclosing the contents of any document, communication or information which relates and has come to the person's knowledge in the course of their duties under the Bill once enacted. The **prohibition** is however not to be construed to prevent the disclosure of criminal activity by a member of the Board or staff of the Agency.
- 82) **Clause 58** requires a person responsible for a matter before the Board of Directors of the Digital Health Agency to cooperate with the Board and, in particular, to respond to any inquiry made by the Board, furnish the Board with a report in respect of the question raised, and provide any other information that the Board may require in the performance of its functions.
- 83) **Clause 59** makes provision for **offenses** under the Bill. It makes it an offense for a person to obstruct, hinder or threaten a member, employee or agent of the Board; disregard an order of the Board; submit false or misleading information to the Board; or make a false representation to, or knowingly misleads a member, employee or agent of Board. The offense attracts a penalty of a fine of not less than one million shillings or imprisonment for not less than two years, or to both such fine and imprisonment. The Bill also provides a similar penalty as a general penalty for offenses under the Bill with no specific penalty.
- 84) **Clause 60** on the other hand makes provision for the development of **regulations**. It empowers the Cabinet Secretary for Health, in consultation with the Digital Health Agency and county governments, to 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
  - d) the establishment and implementation of the data exchange component as per the Kenya Health Enterprise Architecture.
- 85) **Clause 61** mandates persons processing personal data under the Bill, once enacted, to comply with the **Data Protection Act, 2019**.
- 86) **Clause 62** requires persons who were data controllers or data processors of health data or who have been handling health information before the commencement of the Bill once enacted to, within six months of the commencement, comply with the requirements of the Bill.
- 87) **The Schedule to the Bill** details the provisions relating to the conduct of business and the affairs of the Board. It makes provision for the conduct of the affairs of the Board of Directors of the Digital Health Agency. It provides for meetings of the

Board, the election of vice-chairperson, the time and place of meetings, special meetings, quorum for the conduct of business, presiding over meetings, decisions of the Board, vacancy in the Board and significance of instruments and decisions of the Board.

## CHAPTER TWO

### PUBLIC PARTICIPATION ON THE BILL

- 88) Pursuant to the provisions of Article 118 of the Constitution and Standing Order 145 (5) of the Senate Standing Orders, the Standing Committee on Health invited interested members of the public to submit submissions on the Bills.
- 89) An advertisement requesting for submission of memoranda from members of the public was made in the Daily Nation and Standard Newspapers on Wednesday, 4<sup>th</sup> October, 2023. Receipt of memoranda on the Bill was closed on Saturday, 7<sup>th</sup> September, 2023.
- 90) Further to the above, correspondence was dispatched to targeted stakeholders requesting for submission of memoranda and inviting them to appear before the Committee as indicated below -
- a) Government Departments/Agencies
    - Ministry of Health (MoH)
    - Council of Governors (COG)
    - National Health Insurance Fund (NHIF)
    - Insurance Regulatory Authority (IRA)
  - b) Trade Unions
    - Central Organisation of Trade Unions (COTU)
  - c) Private Sector
    - Federation of Kenya Employers (FKE)
    - Kenya Healthcare Federation (KHF)
    - Christian Health Association of Kenya (CHAK)
    - Rural Private Health Association (RUPHA)
    - Association of Kenya Insurers (AKI)
- 91) Further, following the call for submissions, the Committee received written memoranda from various stakeholders, namely: Ministry of Health (MoH); Council of Governors (COG); National Health Insurance Fund (NHIF); Insurance Regulatory Authority (IRA); Central Organisation of Trade Unions (COTU); Federation of Kenya Employers (FKE); Kenya Healthcare Federation (KHF); Christian Health Association of Kenya (CHAK); Rural Private Health Association (RUPHA); Association of Kenya Insurers (AKI); Kenya Union of Clinical Officers (KUCO); Pharmaceutical Society of Kenya (PSK); Confraternity of Patients Kenya; International Budget Partnership - Kenya (IBP-Kenya); Kenya Faith-Based Health Services Consortium; The Actuarial Society of Kenya (TASK); Association of Kenya Medical Laboratory Scientific Officers (AKMLSO); Health NGOs Network (HENNET); International Commission of Jurists (ICJ); Kenya Dental Association (KDA); Health Records and Information Management Professionals (comprising the Health Records and Information Managers Board and the Association of Medical

Records Officers); Civil Society Organisations (comprising the Kenya AIDS NGOs Consortium (KANCO), Amnesty International Kenya, People's Health Movement (PHM) and the Institute of Public Finance (IPF)), Tech Hive Advisory Africa, and Helium Health Limited.

- 92) A matrix with a summary of the submissions from the various stakeholders has been attached to this report as *Annex 6*.
- 93) Further to the above, on Friday, 6<sup>th</sup> October, 2023, the Committee held a stakeholder engagement meeting with various government departments and agencies, private sector groups and faith-based organizations as indicated above (see paragraph '79').
- 94) The **Ministry of Health** submitted that it supported the Bill in its entirety, and that most areas of contention with the Bill as raised by various stakeholders had been addressed by the amendments passed by the National Assembly.
- 95) In their submission on the bill, the **Council of Governors** expressed full support, and recognized that the bills had the potential to revolutionize healthcare delivery and improve patient outcomes through the integration of digital technologies.
- 96) In their submission, the **Insurance Regulatory Authority (IRA)** expressed support for the Bill but nonetheless proposed the following amendments -
  - a) Amend Clause 2 to encompass both medical expenses and health insurance data under the category of 'health-related data information'. This will enable private health insurers and social insurers to price medical health risks.
  - b) Insertion of the words 'for health insurance purposes' in clause 17(d)(iv) in order to enable all health insurers to access the data to make informed decisions.
- 97) The **Federation of Kenya Employers** made submissions as follows -
  - a) Amend the term "data commissioner" means the person appointed under section 6 of the Data Protection Act, 2019 (as amended from time to time), so as not to render the reference obsolete if the referenced Act be amended.
  - b) Replace the word Authority with Agency in Clause 7(2) to cure typo in the name of the Agency;
  - c) Amend clause 8(1)(a) by substituting "one person appointed by the Cabinet Secretary representing the private sector" with "one person nominated by the most representative Employers body, Federation of Kenya Employers and appointed by the Cabinet Secretary to represent the private sector".
- 98) The **Kenya Healthcare Federation** made the following submissions -

- a) Amend clause 2 under consent to include provision of reasonable accommodation for a person with a disability to make informed choices.
- b) Insert the definition of the word “Data Disaggregation” to the interpretation section of the preliminary noting that disaggregating data improves healthcare reports, informs targeted interventions, policies, and enhances data-driven decision-making.
- c) Amend the word Digital Health to the most acceptable and broad meanings of the compound words, ‘digital’ and ‘health’ so as to avoid misinterpretation and ambiguity.
- d) Amend the definition of E-Health under Clause 2 to harmonize the definitions and relationships of the terms digital health, telehealth, telemedicine and E-Health. Compare usage of terms in different jurisdictions, synonyms and interchangeability of definition of terms and usage. Definitions and meanings should be wide enough to include all the meanings of the concepts of Telehealth
- e) Clause 3(g) establishes a regulatory framework for e-waste management: Consider alignment with the Environmental Management and Coordination Act (EMCA) of 1999 on environmental protections. Matters of the environment and how they affect healthcare can be well addressed through the public health and environmental laws.
- f) Insert the definition of the word “National Health Data Dictionary” under clause 2.
- g) Amend the Health Act of 2017 to accommodate the functions of the Digital Health Agency for coherence and consistency.
- h) Delete the word ‘truth’, and replace it with the word ‘reference’ in Clause 6(b).
- i) Define the word “accessibility” to read health data accessibility and portability in Clause 5(e), 6(d) and 6(e) to guarantee seamless access to information as guaranteed in the Constitution and other legal frameworks.
- j) Interchange Clause 7 and 8 for 8 to be 7 or vice versa to improve incoherency in drafting and flow.
- k) Amend Clause 8 (1) to remove the Principal Secretary for ICT, and replace him/her with the Director General for Health.
- l) Explicitly reserve one spot for persons with disabilities or their representative organization in clause 8(j).
- m) Amend Clause 8(1)(f) to read ‘*One person nominated by the Council of Governors from among the County Directors of Health.*’

- n) Amend Clause 8(1)(g) to read h. *'The Director General of Health'*
- o) Amend Clause 8(1)(h) to read *'Two persons appointed by the Cabinet Secretary, one being a representative of patients' interests selected from patient interest groups and the other being a health professional with knowledge and experience in digital health or healthcare related backgrounds.'*
- p) Delete the words *'sentenced to imprisonment for a term exceeding six months'* from Clause 8(4)(d) concerning eligibility for public office.
- q) Deletion of the whole 4(e) in Part II Clause 8 since it is not clear what constitutes mental or physical infirmity.
- r) Deletion of Clause 8(7) since co-option of technical persons into board committees still serves the same purpose as request for consultancy services.
- s) Amend clause 12 to stipulate a person with a Master's degree since a person with a bachelor's degree may not have adequate skills and experience in handling expected mandates.
- t) Insert the qualification of healthcare background under clause 12(1)(b) given that healthcare trained persons excluded have been from the list of qualifications provided.
- u) Introduce term limits under clause 13(1) to include a period of 3 years renewable for a further 3 years.
- v) Amend clause 21(1) to have a one-stop reference for all healthcare-related matters, laws and regulations.
- w) Add disaggregation of data as one of the functions on the proposed Health Information System in Clause 21(3)
- x) Add new categories of data under Clause 25 e.g. AI, to allow for new changes happening in the technological world.
- y) Amend Clause 28 to read custodian of digital health data since information held in the data system can only be referenced as digital health data.
- z) Amend Clause 32 to note that, the data controller appointed by the Cabinet Secretary must be a health professional who understands the vitality of such data and therefore facilitates fast transmission of such data (biological specimens, health images, human tissues and organs) as need be. Additionally, similar qualifications should apply to the data controller at county level.

- aa) Amend clause 33, section 33(j) to provide for the utilization of data targeted healthcare service interventions and programs”.
- bb) Amend clause 36(1)(a) by deleting the word ‘may’ and replacing it with ‘shall’ to control for abuse of discretion by the officer.
- cc) Amend clause 41(1)(e) to reflect that digital health may not be lost by an individual but as a result of system breaches.
- dd) Amend Section 42(1) to include accessible formats and Section 42(2) to accommodate data subjects, ensuring useful, interactive health data and eliminating communication barriers.
- ee) Deletion of the words “mental or other disability” in Clause 44(1)(ii) and adding data subject at the end so that the section reads “by a person duly authorized by the data subject”.
- ff) Deletion of clauses 46-50 as e-petitions are covered under section 105 of the Health Act of 2007; Section 103. Regulations under the Health Act of 2017 can be made to better operationalize e-health and telehealth to minimize re-invention and strengthen existing laws;
- gg) Delete clause of 47 (2)(d) to be in conformity with section 48 of the Data Protection Act of 2019.
- hh) Amend clause 49(1)(h) to avoid disenfranchising persons with disabilities from participating in societal affairs on an equal basis and perpetuating misconceptions about healthcare needs.
- ii) Align provisions on E-Waste management with the Environmental Management Coordination Act (EMCA) of 1999 and the Health Act of 2017.
- jj) Delete provisions on health tourism, and amend the Health Act of 2017 to provide for the operationalization of the different modalities of health tourism.
- kk) Amend the word ‘may’ to ‘shall’ in Clause 57(1) to avoid risking abuse of discretion
- ll) Amendment of Clause 59(1) to align with the Data Protection Act where most concepts in the bill have been borrowed from.

99) The **Confraternity of Patients (COFPAK)** made submissions as follows -

- a) Under the definition of the word ‘health tourism’ insert the words “diagnostic, surgical, dental and mental wellness treatment”. The implication is to provide for clear definition and guidelines on all aspects of health tourism without strict bound to medical services;

- b) Amend clause 8(1) to provide for one person nominated by the Confraternity of Patients Kenya (COFPAK) to represent the interests of patients since COFPAK is the premier patient representative organization in Kenya.
- c) Addition of “informed” before consent in Clause 31 (a) to empower the client/patient in making an informed choice thereby promoting respect and autonomy as a care seeker.
- d) Insertion of the words “orally or in writing” after healthcare provider in Clause 31 (4) to provide for clear means through which an individual is able to withdraw their consent at any time of the process of personal data handling.
- e) Delete the word “Sensitive” in Clause 35(g) to take into consideration that any personal Data is sensitive Data and must not be shared

100) **International Budget Partnership Kenya** made the following submissions -

- a) The E-Health Bill, 2023 and Digital Health Bill share similarities but differ in clarifying national and county government roles in digital health. The Senate should draw from the E-Health Bill, 2023 to define national and county governments' roles in digital service delivery. This is a vital step in ensuring the right level of government is budgeting and investing for the assigned function in the Constitutions and as may be defined in this law;
- b) In the Memorandum of Objects and Reasons, the bill acknowledges potential additional public expenditure. This has resource implications for both the national and county governments, especially concerning the national government establishment and operation of the Digital Health Agency and county health data banks and other costs.
- c) Clause 6(f) empowers the Agency to gather and analyze data for health policy and research. Clause 25 classifies health data, including research for health data, but prohibits the disclosure of health data (personal health information) for market research Clause 44(2). Questions arise about who can access health research data and whether fees will be involved. Charging fees could fund data system maintenance but might risk unethical data selling unless properly standardized.
- d) Clause 49 (b) states that; A healthcare provider shall ensure that the interaction in the e-health platform is undertaken in a manner that respects rights as prescribed by law. However, questions arise about third-party platforms' role and implementation. For instance, therapy sessions on Zoom by psychologists: Will providers need to create their own platforms? How does this align with health information systems?

- e) Clause 3(a) establishes the Digital Health Agency as the national custodian of data, raising concerns about its impact on county healthcare, primarily a devolved function. This raises other questions about access to information procedures for both National and County Governments: Whether the information will be open to all counties for cross county learning or unique to every county, and the distinction between integrated health under Clause 3(b) and management information systems according to Clause 6(b). Clarity is needed regarding integration with existing systems like Kenya Health Management Information System (KeHMIS), Integrated Human Resource Information System (IHRIS), Human Resource for Health (HRH), and National Health Accounts, to ensure seamless coordination and compatibility;
- f) Clause 19 lays out the annual reporting requirements for the agency and places the weight on the Chief Executive Officer. However, the bill does not place a requirement on the reports being Tabled in Parliament as well as being published and publicized in line with the PFM Act on agency funded by taxpayers;
- g) Under general observations, the bill should align with existing laws to enhance, not duplicate, data collection efforts. Collaboration with the Kenya National Bureau of Statistics is crucial. Secondary legislation may be necessary to address technology-related harms, but it's unclear if the bill includes such provision. To ensure service quality, the bill should also address the training and skills of health professionals while setting e-health service standards.

101) The **Kenya Faith-Based Health Services Consortium (KCCB, CHAK, MEDS and SUPKEM)** made the following submissions -

- a) Amend clause 13(2) in consideration that the 5-year term is not consistent with other proposed terms in similar parastatals. Further, insert the term ' 3 years renewable once'' in line with other health Bills.
- b) Delete clause 13(4) on grounds that it is not a competitive process and such an office should go through interviews like others.
- c) Amend clause 28(2) on County Health Databank and centralize this with the National Government, with limited delegated roles to the counties to avoid duplication of Agency roles and the county.

102) The minutes of the Committee meetings on the Bill have been attached to this report as *Annex 1*. In addition, a schedule of the meetings held with the aforementioned stakeholders has been attached to this report as *Annex 5*.

103) A matrix with a summary of the submissions from the various stakeholders has been attached to this report as *Annex 6*.

104) The Committee proceeded to consider the Bill and the submissions received thereon as set out in the matrix attached to this report as *Appendix 7*.

## CHAPTER THREE

### COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

#### A. Committee Observations

105) The Committee, having considered the Digital Health Bill, 2023, National Assembly Bill No. 57 of 2023 and submissions from stakeholders, made the following observations:

- a) Article 43 of the Constitution of Kenya guarantees all citizens the right to the highest attainable standard of health. This includes access to reproductive health care, and emergency medical treatment. The Bill facilitates the realization of the right to health by leveraging on IT to drive responsiveness, efficiency, transparency and seamless provision of health services as a key enabler for the attainment of UHC. It further presents a vital response to a rapidly evolving landscape of healthcare in the digital era, where digital technologies are increasingly shaping the way healthcare services are delivered and managed.
- b) The Bill facilitates the realization of the right to protection of personal information as guaranteed under Article 31 of the Constitution of Kenya, 2010 and under the Data Protection Act, No. 24 of 2019.
- c) Pursuant to section 105 of the Health Act, 2017, which obligates the Cabinet Secretary to establish an integrated comprehensive health information system in relation to national and county health functions, the Bill seeks to establish a comprehensive integrated digital health information system, and to consolidate and harmonize information obtained from both levels of government;
- d) The Bill addresses the urgent need to establish a robust legal framework that aligns with the digital transformation of healthcare systems, and aims to: set out clear guidelines and regulations for the adoption, management, and safeguarding of digital health information; enhance patient-centered care; streamline healthcare operations; and, leverage on real-time data to draw timely insights to improve health outcomes.
- e) It sets the minimum standards applicable for the establishment and maintenance of digital health information systems. It further provides the mechanism for inter-connectivity between each county information system 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.
- f) It enhances the health data governance framework in the country by requiring health care providers and health facilities to adopt mechanisms to ensure the safety and security of patient information.

- g) It gives Kenyans the ability to have more control over their personal data as it mandates consent before the collection, processing and sharing of their personal health related information;
- h) The Bill further regulates the processing of health data and in particular health data that contains sensitive personal data, through technological mediums such as telemedicine. In this regard, the Bill requires health care providers and technology platforms that offer telemedicine to put in place several safeguards including anonymization and de-identification of sensitive personal data. In this way, the Bill regulates the largely unregulated telemedicine and e-health platforms among others, which will guarantee the safety of Kenyans using such platforms.
- i) Majority of the concerns raised by stakeholders with regards to the Bill during public participation had already been addressed in the amendments passed the National Assembly. For example, whereas stakeholders raised concerns regarding the qualifications for appointment as a Chief Executive Officer (CEO) of the Digital Health Agency, the Committee found that the Bill as passed by the National Assembly required the CEO to have a Master's Degree, and at least ten years' knowledge and experience in a relevant field.
- j) It was further the observation of the Committee that, considering the rapidly evolving landscape of digital healthcare, other concerns raised by stakeholders during public participation would be more appropriately addressed through regulations, rules and guidelines.

## **B. Committee Recommendations**

- 106) The Committee therefore recommends that the Senate **passes the Bill without amendments.**



**MINUTES OF THE NINETY-FIRST SITTING OF THE STANDING COMMITTEE ON HEALTH HELD ON MONDAY 9<sup>TH</sup> OCTOBER, AT 1.15 PM, ON THE ZOOM ONLINE MEETING PLATFORM.**

**PRESENT**

- |   |   |                         |
|---|---|-------------------------|
| 1. Sen. Jackson Kiplagat Mandago, EGH, MP | - | <b>Chairperson</b>      |
| 2. Sen. Mariam Sheikh Omar, MP            | - | <b>Vice-Chairperson</b> |
| 3. Sen. Erick Okong'o Mogeni, SC, MP      | - | Member                  |
| 4. Sen. Raphael Chimera, MP               | - | Member                  |
| 5. Sen. Joseph Nyutu Ngugi, MP            | - | Member                  |
| 6. Sen. Hamida Kibwana, MP                | - | Member                  |
| 7. Sen. Esther Anyieni Okenyuri, MP       | - | Member                  |

**ABSENT WITH APOLOGIES**

- |                                |   |        |
|--------------------------------|---|--------|
| 1. Sen. Ledama Olekina, MP     | - | Member |
| 2. Sen. Abdul Mohamed Haji, MP | - | Member |

**SECRETARIAT**

- |                          |   |                   |
|--------------------------|---|-------------------|
| 1. Dr. Christine Sagini  | - | Committee Clerk   |
| 2. Ms. Florence Waweru   | - | Clerk Assistant   |
| 3. Mr. Mitch Otoro       | - | Legal Counsel     |
| 4. Mr. Jackson Wekesa    | - | Legal Counsel     |
| 5. Ms. Annette Khayela   | - | Research Officer  |
| 6. Ms. Brenda Wekesa     | - | Research Officer  |
| 7. Mr. Victor Kimani     | - | Audio Officer     |
| 8. Ms. Gladys Chombo     | - | Protocol Officer  |
| 9. Ms. Lilian Onyari     | - | Fiscal analyst    |
| 10. Mr. Ibrahim Mohammed | - | Sergeant –at-arms |

**MIN/SEN/SCH/505/2023**

**PRELIMINARIES**

The meeting was called to order at 1.15 p.m. with a word of prayer from the Chairperson.

1 XSMMA

MIN/SEN/SCH/506/2023

ADOPTION OF AGENDA

The Agenda was adopted as proposed by Sen. Mariam Sheikh Omar, MP and seconded by Sen. Hamida Kibwana, MP as follows;

1. Prayer;
2. Adoption of the Agenda;
3. Confirmation of minutes of the sitting held on Friday, 6<sup>th</sup> October, 2023;
4. Matters arising from previous minutes;
5. Consideration and adoption of the Committee Reports on the -
  - a) The Digital Health Bill (National Assembly Bill No.57 of 2023); and
  - b) The Social Health Insurance Bill (National Assembly No. 58 of 2023)
5. Any other business;
6. Adjournment/Date of the Next Meeting.

MIN/SEN/SCH/507/2023

CONSIDERATION AND ADOPTION OF THE COMMITTEE REPORTS ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)

1. The Committee considered and adopted the Report on Digital Health Bill (National Assembly Bills No. 57 of 2023) having been proposed by Sen. Raphael Chimera, MP, and seconded by Sen. Esther Okenyuri, MP; and
2. The Committee considered and adopted the Report on the Social Health Insurance Fund (National Assembly Bills No. 58 of 2023) having been proposed by Sen. Joe Nyutu, MP, and seconded by Sen. Mariam Sheikh Omar, MP.

MIN/SEN/SCH/503/2023

ANY OTHER BUSINESS

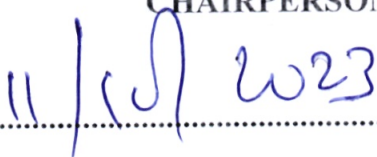
There was no other business.

MIN/SEN/SCH/504/2023

ADJOURNMENT

There being no other business, the meeting was adjourned at 2.05 pm. The next meeting was scheduled on notice.

SIGNED: .....  
CHAIRPERSON

DATE: .....



**MINUTES OF THE NINETIETH SITTING OF THE STANDING COMMITTEE ON HEALTH HELD ON MONDAY 9<sup>TH</sup> OCTOBER, AT 10.00AM, ON THE ZOOM ONLINE MEETING PLATFORM.**

**PRESENT**

1. Sen. Jackson Kiplagat Mandago, EGH, MP	-	<b>Chairperson</b>
2. Sen. Mariam Sheikh Omar, MP	-	<b>Vice-Chairperson</b>
3. Sen. Erick Okong'o Mogeni, SC, MP	-	Member
4. Sen. Ledama Olekina, MP	-	Member
5. Sen. Raphael Chimera, MP	-	Member
6. Sen. Joseph Nyutu Ngugi, MP	-	Member
7. Sen. Abdul Mohamed Haji, MP	-	Member
8. Sen. Hamida Kibwana, MP	-	Member
9. Sen. Esther Anyieni Okenyuri, MP	-	Member

**SECRETARIAT**

1. Dr. Christine Sagini	-	Committee Clerk
2. Ms. Florence Waweru	-	Clerk Assistant
3. Mr. Mitch Otoro	-	Legal Counsel
4. Mr. Jackson Wekesa	-	Legal Counsel
5. Ms. Annette Khayela	-	Research Officer
6. Ms. Brenda Wekesa	-	Research Officer
7. Mr. Victor Kimani	-	Audio Officer
8. Ms. Gladys Chombo	-	Protocol Officer
9. Ms. Lilian Onyari	-	Fiscal analyst
10. Mr. Ibrahim Mohammed	-	Sergeant –at-arms

**MIN/SEN/SCH/497/2023**

**PRELIMINARIES**

The meeting was called to order at 10.30 a.m. with a word of prayer from the Chairperson.

MIN/SEN/SCH/498/2023

ADOPTION OF AGENDA

The Agenda was adopted as proposed by Sen. Mariam Sheikh Omar, MP and seconded by Sen. Hamida Kibwana, MP as follows;

1. Prayer;
2. Adoption of the Agenda;
3. Confirmation of minutes of the sitting held on Friday, 6<sup>th</sup> October, 2023;
4. Matters arising from previous minutes;
5. Overview and consideration of memoranda matrix on the Digital Health Bill (National Assembly Bill No.57 of 2023) and the Social Health Insurance Bill (National Assembly No. 58 of 2023) (*Committee Paper No.48*);
5. Any other business;
6. Adjournment/Date of the Next Meeting.

MIN/SEN/SCH/499/2023

CONFIRMATION OF MINUTES OF THE SITTING HELD ON FRIDAY, 6<sup>TH</sup> OCTOBER, 2023

The minutes of the 89<sup>th</sup> sitting held on Friday, 6<sup>th</sup> October, 2023 were confirmed to be a true record of the deliberations having been proposed by Sen. Esther Anyieni Okenyuri, MP and seconded by Sen. Mariam Sheikh Omar, MP.

MIN/SEN/SCH/500/2023  
MINUTES

MATTERS ARISING FROM PREVIOUS

There were no matters arising.

MIN/SEN/SCH/501/2023

OVERVIEW AND CONSIDERATION OF MEMORANDA MATRIX ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILL NO.57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY NO. 58 OF 2023) (COMMITTEE PAPER NO.48);

The committee considered the matrices on public participation under each Bill and noted the following -

**a) Under the Digital Health Bill (National Assembly Bill No.57 Of 2023)**

1. On the composition of the Digital Health Agency Board, Members noted that there was a need to further prescribe the criteria for the three representatives of the Council of Governors to ensure technical skill and competence. Members proposed making such specifications as a representative of the County Executive Committee Health Caucus, or the Chief Officer of Health Caucus.
2. Members further noted that several stakeholders had requested for representation on the Board. Noting that this was an issue that cut across several parastatals, Members noted that there was a need to review the composition of Boards in general, and to propose amendments to the State Corporations Act.
3. Noting the similarities between the Digital Health Bill, 2023, and the County E-Health Bill sponsored by Sen. Hamida Kibwana, MP, Members noted that there was a need to harmonize the two Bills with a view to ensuring the prudent use of public resources.

**b) Under the Social Health Insurance Bill (National Assembly No. 58 of 2023)**

1. Members noted that the rate of contributions should be specified in the law rather than be left to regulations.
2. Provisions ought to be made under the Transitional Provisions to guarantee no loss of livelihood for current NHIF staff.
3. Members further noted that several stakeholders had requested for representation on the Board. Noting that this was an issue that cut across several parastatals, Members noted that there was a need to review the composition of Boards in general, and to propose amendments to the State Corporations Act.
4. Members noted general concerns arising from provisions on registration, contributions, fines, penalties and the enhanced schemes and noted that they could be addressed where necessary, following the roll-out and implementation of the Bill.

Following extensive deliberations on the two Bills, the Committee resolved to adopt the Bills without amendments, and to address the issues raised in the Bills once they were assented to.

**MIN/SEN/SCH/503/2023**

**ANY OTHER BUSINESS**

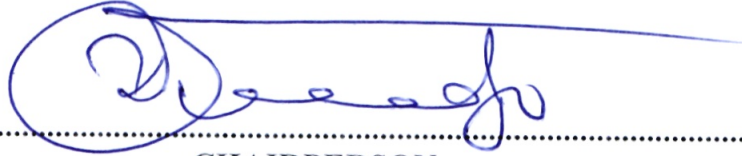
There was no other business.

MIN/SEN/SCH/504/2023

ADJOURNMENT

There being no other business, the meeting was adjourned at 1.30 pm. The next meeting was scheduled for 1.45 pm.

SIGNED: .....



CHAIRPERSON

DATE: .....

11/10/2023



**MINUTES OF THE EIGHTY-NINTH SITTING OF THE STANDING COMMITTEE ON HEALTH HELD ON FRIDAY 6<sup>TH</sup> OCTOBER, AT 10.00AM AT SENATE CHAMBER, MAIN PARLIAMENT BUILDINGS.**

**PRESENT**

1. Sen. Jackson Kiplagat Mandago, EGH, MP	-	<b>Chairperson</b>
2. Sen. Mariam Sheikh Omar, MP	-	<b>Vice-Chairperson</b>
3. Sen. Abdul Mohamed Haji, MP	-	Member
4. Sen. Raphael Chimera, MP	-	Member
5. Sen. Hamida Kibwana, MP	-	Member
6. Sen. Esther Anyieni Okenyuri, MP	-	Member

**ABSENT WITH APOLOGY**

1. Sen. Erick Okong'o Mogeni, SC, MP	-	Member
2. Sen. Ledama Olekina, MP	-	Member
3. Sen. Joseph Nyutu Ngugi, MP	-	Member

**SECRETARIAT**

1. Dr. Christine Sagini	-	Clerk Assistant
2. Ms. Florence Waweru	-	Clerk Assistant
3. Mr. Mitch Otoro	-	Legal Counsel
4. Mr. Jackson Wekesa	-	Legal Counsel
5. Ms. Annete Kwamboka	-	Legal Counsel
6. Mr. Victor Kimani	-	Audio Officer
7. Mr. Ngeno	-	Media Relations
8. Ms. Gladys Chombo	-	Protocol Officer
9. Ms. Lilian Onyari	-	Fiscal analyst
10. Mr. Ibrahim Mohammed	-	Sergeant –at-arms

**INATTENDANCE (see attached attendance register)**

**1. Ministry of Health**

a) Mr. Harry Kimtai	-	Principal Secretary State Department of Medical Services
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- b) Ms. Terry Rotich - State Legal Counsel
- c) Dr. Elizabeth Wangia - Ag, Director Health Financing
- d) Dr. Joyce Wamicwe - Directorate of Digital Health

## **2. Council of Governors**

- a) Hon. Mutahi Kahiga - Governor Nyeri – Chairperson, Human Resource, Labour and Social Welfare Committee, COG
- b) Ms. Irene Ogamba - Director
- c) Ms. Mabel Abuor - Official
- d) Ms. Naomi Kefa - Legal Counsel

## **3. National Hospital Insurance Fund- NHIF**

- a) Dr. Samson Kuhora
- b) Ms. Evelyne Khamase
- c) Mr. Chrisostim Wafula

## **4. Insurance Regulatory Authority- IRA**

- a) Ms. Diana Sawe Tanui - Corporation Secretary
- b) Ms. Teresa Mburu
- c) Mr. Wilson Wachira

## **5. Federation of Kenyan Employers- FKE**

- a) Ms. Jackline Mugo - Chief Executive Officer
- b) Dr. Rachel - Board Member
- c) Mr. Stephen Obiro - Head of advocacy
- d) Mr. Samson Mugwe - Head Finance

## **6. Christian Health Association of Kenya- CHAK**

- a) Dr Sama Omwenda - General Secretary
- b) Mr. Moses Mukua
- c) Mr. Jeophrey Mwalo

## **7. Rural Private Hospital Association of Kenya-RUPHA**

- a) Dr. Brian Lishenga - Chairman
- b) Ms. Cynthia Munene - Chief Executive Officer

## **8. International Budget Partnership of Kenya- IBP**

- a) Mr. John Kinuthi
- b) Ms. Nancy Ndanu
- c) Ms. Faith Ann Kinyanjui
- d) Ms. Cuba Hatson

## **9. Confraternity of Patients Kenya (COFPAK)**

- a) Mr. Joab Ogallo - Chairperson
- b) Ms. Winfred Wagura - Secretary

## **10. Association of Kenya Insurers (AKI)**

- a) Mr. Kiama William
- b) Ms. Lynne Obwanda

## **11. Kenya Healthcare Federation**

- 1. Dr. Kanyenje Gakombe
- 2. Mr. Peter Kanda
- 3. Ms. Idah Kabukuru
- 4. Dr. Jane Kyula

## **12. Kenya Association of Private Hospitals (KAPH)**

- a) Dr. Abdi Mohamed - Chairperson

## **13. Kenya Union of Nutritionists and Dietitians**

- a) Ms. Lilian Mumina - National Treasurer

## **14. Kenya Union of Clinical Officers**

- a) Ms. Mary Boniface
- b) Mr. Odongo Okatch
- c) Mr. Peter Mulwo
- d) Mr. Veyeni Moses

**MIN/SEN/SCH/491/2023**

**PRELIMINARIES**

The meeting was called to order at 10.30 a.m. with a word of prayer from the Chairperson.

**MIN/SEN/SCH/492/2023**

**ADOPTION OF AGENDA**

The Agenda was adopted as proposed by Sen. Mariam Sheikh Omar, MP and seconded by Sen. Hamida Kibwana, MP as follows;

1. Prayer;
2. Adoption of the Agenda;
3. Committee Paper on the Digital Health Bill (National Assembly Bill No.57 of 2023) and the Social Health Insurance Bill (National Assembly No. 58 of 2023) (*Committee Paper No.47*);
4. Submission of memoranda on the Digital Health Bill (National Assembly Bill No.57 of 2023) and the Social Health Insurance Bill(National Assembly No. 58 of 2023) by-
  - a. Ministry of Health;
  - b. Council of Governors(CoG);
  - c. National hospital Insurance Fund(NHIF);
  - d. Insurance Regulatory Authority (IRA);
  - e. Central Organization of Trade Unions (COTU);
  - f. Federation of Kenya employers (FKE);
  - g. Christian Health Association of Kenya (CHAK);
  - h. Rural Private Hospitals Association of Kenya(RUPHA);
  - i. International Budget Partnership, Kenya (IBP);
  - j. Confraternity of Patients Kenya (COFPAK); and
  - k. Association of Kenya Insurers (AKI);
5. Any other business;
6. Adjournment/Date of the Next Meeting.

**MIN/SEN/SCH/493/2023**

**COMMITTEE PAPER ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILL NO.57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY NO. 58 OF 2023) (COMMITTEE PAPER NO. 47)**

The Committee considered and took note of the contents of Committee Paper No. 47 on the Digital Health Bill (National Assembly Bills No. 57 of 2023) and the Social Health Insurance Bill (National Assembly No.58 Of 2023).

The Chairperson then opened the meeting with a note of appreciation for the prompt attendance. He highlighted the importance of the Bills before the Committee in the achievement of the National Government legislative agenda on Universal Health coverage. This was followed by a round of introductions of all present.

**MIN/SEN/SCH/494/2023**

**SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILL NO.57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL**

(NATIONAL ASSEMBLY NO. 58 OF 2023)( all  
memoranda annexed)

The Chairperson opened the session for submission of memoranda. The memoranda received on each Bill and discussions therein are summarized per the attached matrix.

MIN/SEN/SCH/495/2023      ANY OTHER BUSINESS

The Committee resolved to hold an online meeting on Monday, 9<sup>th</sup> October, 2023 for purposes of consideration and adoption of the Bills' reports in readiness for laying in the house on Wednesday, 11<sup>th</sup> October, 2023.

MIN/SEN/SCH/496/2023      ADJOURNMENT

There being no other business, the meeting was adjourned at 3.00 p.m. The next meeting will be on Monday, 9<sup>th</sup> October, 2023.

SIGNED:  .....

CHAIRPERSON

DATE:  .....

Annex 2



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REPUBLIC OF KENYA

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PARLIAMENT

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NATIONAL ASSEMBLY BILLS  
(Bill No. 57 of 2023)

THE DIGITAL HEALTH BILL, 2023

(A Bill published in the Kenya Gazette Supplement No. 163 of 2023 and passed by the National Assembly, with amendments, on September 27<sup>th</sup>, 2023)

N.A. /B/No. 57/2023

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Exam

**THE DIGITAL HEALTH BILL, 2023**  
**ARRANGEMENT OF CLAUSES**

*Clause*

**PART I—PRELIMINARY**

- 1—Short title.
- 2—Interpretation.
- 3—Objects of the Act.
- 4—Guiding principles.

**PART II—ESTABLISHMENT OF THE DIGITAL  
HEALTH AGENCY**

- 5—Establishment of the Digital Health Agency.
- 6—Functions of the Agency.
- 7—Powers of the Agency.
- 8—Board of Directors.
- 9—Conduct of business and affairs of the Board.
- 10—Committees of the Board.
- 11—Chief Executive Officer.
- 12—Qualification for appointment as a Chief Executive Officer.
- 13—Corporation Secretary.
- 14—Staff.

**PART III—ESTABLISHMENT AND  
ADMINISTRATION OF THE COMPREHENSIVE  
INTEGRATED HEALTH INFORMATION SYSTEM**

- 15—Establishment of a comprehensive integrated health information system.
- 16—Components of the system.
- 17—Objectives of the system.
- 18—Technical aspect of the system.

**PART IV—HEALTH DATA GOVERNANCE**

- 19—Classification of health data

- 20— Governing principles
- 21—Establishment of health data governance framework.
- 22—Health data custodian.
- 23—Health data use.

**PART V—CONFIDENTIALITY, PRIVACY AND SECURITY OF DATA**

- 24—Security, privacy and disclosure of data in the system.
- 25—Retention and disposal of data in the system.
- 26—Establishment of health data banks.
- 27—Use of sensitive personal data.
- 28—Responsibilities of health data bank controller.
- 29—Request for information by authorized person.
- 30—Disclosure of sensitive personal data of deceased persons.
- 31—Consent.
- 32—Processing of personal data relating to a minor or a person without capacity.
- 33—Duty to protect sensitive personal data.
- 34—Disposal of health information.
- 35—Breach of health data.
- 36—Health data portability.
- 37—Refusal to grant access to sensitive personal data.
- 38—Precautions on release of sensitive personal health data.
- 39—Right to rectification or erasure.

**PART VI—E-HEALTH SERVICE DELIVERY**

- 40—E-Health service as a mode of health service delivery.

- 41—Provision of e-health services.
- 42—Principles and objectives of e-health.
- 43—E-health services.
- 44—Reporting.

**PART VII—E-WASTE MANAGEMENT**

- 45—E-waste management.

**PART VIII—HEALTH TOURISM**

- 46—Development of guidelines on health tourism.
- 47—Disclosure of sensitive personal data to organisations outside Kenya.

**PART IX—FINANCIAL PROVISIONS**

- 48—Funds of the Agency.
- 49—Financial year.
- 50—Annual estimates.
- 51—Accounts and Audit.
- 52—Annual report.
- 53—Bank account.
- 54—Investment of Funds.

**PART X—MISCELLANEOUS PROVISIONS**

- 55—Protection from personal liability.
- 56—Conflict of interest.
- 57—Confidentiality.
- 58—Duty to cooperate.
- 59—Offences.
- 60—Regulations.
- 61—Compliance to Data Protection Act, 2019.
- 62— Transitional provision.

**SCHEDULE—CONDUCT OF THE BUSINESS AND  
AFFAIRS OF THE BOARD**

## THE DIGITAL HEALTH BILL, 2023

### A Bill for

**AN ACT of Parliament to provide for the establishment of the Digital Health Agency; to provide a framework for provision of digital health services; to establish a comprehensive integrated digital health information system; and for connected purposes**

**ENACTED** by Parliament of Kenya as follows—

### PART I- PRELIMINARY

1. This Act may be cited as the Digital Health Act, 2023. Short title.
2. In this Act, unless the context otherwise requires— Interpretation.
  - “Agency” means the Digital Health Agency established under section 5;
  - “anonymization” means the removal of personal identifiers from personal data so that the data subject is no longer identifiable;
  - “Board” means the Board of Directors of the Agency constituted under section 8;
  - “Cabinet Secretary” means the Cabinet Secretary for ministry responsible for matters relating to health;
  - “client” means an individual who uses, or has used, a health service, or in relation to whom health data has been created;
  - “consent” has the meaning assigned to it under the Data Protection Act, 2019; No. 24 of 2019.
  - “County Executive Committee Member” means the member of county executive committee appointed and designated to supervise health services;
  - “data” means information which—
    - (a) is processed by means of equipment operating automatically in response to instructions given for that purpose;
    - (b) is recorded with intention that it should be processed by means of such equipment;

(c) is recorded as part of a relevant filing system;

(d) is recorded information which is held by a public entity and does not fall within any of paragraphs (a) to (d);

“data analysis” means the process of inspecting, cleaning, transforming, consolidation and modelling of data with the goal of discovering useful information, extracting meaningful insights, suggesting conclusions and supporting decision making;

“data bank” means an organised collection of data designed to efficiently store and retrieve data that can be accessed, managed and updated electronically to allow users to easily search for and access the information they need, to derive insights, make informed decisions and improve performance;

“data commissioner” means the person appointed under section 6 of the Data Protection Act, 2019; No. 24 of 2019.

“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 of personal data;

“data disposal” means the process of destroying manual or electronic records or data completely without being used or accessed for an authorized purpose;

“data governance” means the overall management of the availability, usability, integrity and security of data used in an organization;

“data integrity” means the overall completeness, accuracy and consistency of data;

“data life cycle” means the stages through which data passes from its creation or acquisition to its eventual deletion or archival;

“data management” means the development, execution and supervision of plans, policies, programs and practices that control, protect, deliver and enhance the value of data and information assets, and involves policy formulation and adherence to data management procedures such as reporting rates, harmonized and standard data collection tools;

“data privacy” means the aspect of information technology that deals with the ability an organization or individual has to determine what data in a computer system can be shared with third parties for purposes of the keeping of information private and safe;

“data processor” means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the data controller;

“data reporting” means the process of collection, submission and organisation of data into informational summaries in order to monitor performance;

“data retention” means the continued storage of an organization’s data for compliance with national policy guidelines and regulations;

“data security” means protection of electronic health data, and specifically the means used to protect the privacy of health information contained in electronic health data that supports professionals in holding that information in confidence;

“data storage” means the recording of information in a storage medium or holding information in digital format;

“data subject” means an identified or identifiable natural person who is the subject of personal data;

“de-identification” means removing or hiding personal information from records in such a way that the remaining information cannot be used to identify an individual;

“data verification” includes the authentication and validation of gathered data, data quality checks, audit of the health data using the data quality protocols;

“digital health” means the field of knowledge and practice that is associated with the development and use of digital technologies to improve health;

“Director-General” means the Director-General for health appointed under section 16 of the Health Act, 2017;

No. 21 of 2017.

“disclosure” means submission of relevant information to an authorized party;

“e-Health” means the combined use of electronic communication and information technology in the health

sector including telemedicine;

“e-Health ecosystem” means the combined application of e-Health infrastructure, standards, technology, systems applications, investment, health workforce and governance that support patient-centred models of healthcare;

“e-Health platform” means an ecosystem of hardware, software and technology used to deliver e-Health services;

“electronic health data” means an electronic record of personal health related information about an individual and shall include—

- (a) information concerning the physical or mental health of the individual;
- (b) information concerning any health service provided to the individual;
- (c) information concerning the donation by the individual of any body part or any bodily substance;
- (d) information derived from the testing or examination of a body part or bodily substance of the individual;
- (e) information that is collected in the course of providing health services to the individual; or
- (f) information relating to details of the health facility accessed by the individual;

“encryption” means the process of converting the content of any readable data using technical means into coded form;

“enterprise class” refers to applications that are designed to be robust and scalable across a large organization, and compatible with existing databases and tools, customizable for the needs of specific departments, powerful enough to scale up along with the needs of the business using it, secure from outside threats and data leaks;

“enterprise service bus” means an architectural pattern whereby a centralized software component performs integrations between applications; transformations of data models, handles connectivity, message routing, converts communication protocols and potentially manages the

composition of multiple requests and may make these integrations and transformations available as a service interface for reuse by new applications;

“e-waste” means waste resulting from electrical and electronic equipment including components and sub-assemblies thereof;

“guardian” means a guardian recognised under any law for the time being in force;

“health care professional” includes any person who has obtained health professional qualifications and licensed by the relevant regulatory body;

“health care provider” has the meaning assigned to it under the Health Act, 2017;

“health care services” has the meaning assigned to it under the Health Act, 2017;

“health data” means data related to the state of physical or mental health of the 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;

“health 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 of health data;

“health data custodian” means a person or organization that possesses legal custody over health data;

“health data processor” means a person, public authority, agency or other body who is an authorised worker to process health data;

“health facility” has the meaning assigned to it under the Health Act, 2017;

“health informatics” means the practice of acquiring, studying and managing health data and applying medical concepts in conjunction with health information technology systems to help health professionals provide better healthcare;

“health information bank” means an electronic database under the custody and control of the Ministry of

Health that contains personal health information and is designated by the Cabinet Secretary as a health information bank;

“health information system” means a health ecosystem designed to manage health and health related system data that provides the foundations for decision-making and includes a system that collects, collates, stores, manages, analyses, synthesises, transmit patient's or client's electronic health record and uses health and health related data for operational management or a system supporting healthcare policy decisions;

“health records and information management” means the practice of acquiring, analysing and protecting digital and traditional medical information vital to providing quality patient or client care;

“health records and information manager” means an officer trained in health records and information management and charged with the responsibility of managing health records and health information for the health services which include—

- (a) creating and enforcing policies for effective data management;
- (b) clinical coding and classifications;
- (c) coding for health insurance firms;
- (d) health information management;
- (e) health administrative data and medical data analytics and research;
- (f) appraisal of medical documentations and audits;
- (g) advice on medical legal issues;
- (h) advise on retrieval and disposal of Health and medical records;
- (i) use of e-Health applications;

“health related data information” means the service delivery and administrative health data collected, analysed and synthesised for decision making in the health sector;

“health system” means an organization of people, institutions and resources that deliver health care services

to meet the health needs of the population, in accordance with established policies;

“health technology” means the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life;

“health tourism” means a situation where a patient travels across international borders to receive medical treatment;

“individual” means data subject;

“integrated e-Health information system” means a health information system that collects health and health related data that addresses the needs of all users for decision making;

“Kenya Health Enterprise Architecture” means a blueprint that guides the design, development and evolution of the comprehensive integrated health information system to align investments in technology, information and processes that are cost-effective, sustainable, and aligned with the Kenya health sector strategic goals;

“medical equipment data” means data relating to a medical equipment and contains manufacturer-provided information and client-created inventory information about such equipment and may include exhaust digital data and individual data that may be classified as sensitive data under the Data Protection Act, 2019;

“m-Health” means the delivery of medical services using mobile technologies;

“personal data” means any information relating to an identified or identifiable natural person;

“personal data breach” means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed;

“personal health data” means any information relating to the state of physical or mental health of an identified or identifiable person and includes records on the past, present or future state of that person’s health;

“personal health information” means data related to the state of physical or mental health of an individual and includes information provided by the client, 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 individual to the provision of specific health services;

“personally identifiable information” means information that can be used to uniquely identify, contact or locate an individual, or can be used with other sources to uniquely identify a person;

“private health services” means provision of health services by a health facility that is not owned by the national or county governments and includes health care services provided by individuals, faith-based organizations, non-governmental organizations and private for profit health institutions;

“processing” means any operation or sets of operations which is performed on personal data or on sets of personal data whether or not by automated means including—

- (a) collection, recording, organisation or structuring;
- (b) storage, adaptation or alteration;
- (c) retrieval, consultation or use;
- (d) disclosure by transmission, dissemination or otherwise making available; or
- (e) alignment or combination, restriction, erasure or destruction.

“pseudo-anonymization” means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific individual without the use of additional information, and such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data is not attributed to an identified or identifiable natural person;

“public health services” means health services owned and offered by the national and county governments;

“referral” means the process by which a given health facility transfers a client service, specimen and client parameters to another facility to assume responsibility for

consultation, review or further management;

“research for health” includes research which seeks to contribute to the extension of knowledge in any health related field, such as that concerned with the biological, clinical, psychological or social processes in human beings improved methods for the provision of health services; human pathology; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and other preventative, therapeutic or curative agents; or the development of new applications of health technology;

“system” means the comprehensive integrated health information system established under section 15;

“system integration” refers to the merging or combining of two or more components or configuration items into a higher level system element and ensuring that the logical and physical interfaces are satisfied and that the integrated system satisfies its intended purpose;

“system interoperability” refers to the capability to communicate, execute programs or transfer data among various functional units such that the user needs little or no knowledge of the unique characteristics of those units;

“telehealth” means the use of electronic information and telecommunications technologies including videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications, to support long-distance clinical health care, patient and professional health-related education, public health and health administration;

“telemedicine” refers to the provision of health care services and sharing of medical knowledge over distance using telecommunications and includes consultative, diagnostic, and treatment services; and

“third party” means natural or legal person, public authority, agency or other body, other than the data subject, data controller, data processor or persons who, under the direct authority of the data controller or data processor, are authorised to process personal data.

3. The objects of this Act are to—

Objects of the  
Act.

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

4. In implementing the Act, all persons shall be guided by the following principles—

Guiding principles.

- (a) health data is a strategic national asset;
- (b) safeguard of the privacy, confidentiality and security of health data for information sharing and use;
- (c) digital health shall facilitate data sharing and use for informed decision-making at all levels; and
- (d) the digital health ecosystem shall serve the health sector and facilitate in a progressive and equitable manner, the highest attainable standard of health.

## **PART II— ESTABLISHMENT OF THE DIGITAL HEALTH AGENCY**

5. (1) There is established an Agency to be known as the Digital Health Agency.

Establishment of the Digital Health Agency.

(2) The Agency shall be a body corporate with perpetual succession and a common seal and shall, in its corporate name, be capable of—

- (a) suing and being sued;
- (b) taking, purchasing or otherwise acquiring, holding, charging and disposing of movable and immovable property;
- (c) receiving, investing, borrowing money; and
- (d) doing or performing such other things or acts necessary for the proper performance of its functions under this Act.

6. The Agency shall—

Functions of the Agency.

- (a) develop, operationalise and maintain the Comprehensive Integrated Health Information System to manage the core digital systems and the infrastructure required for its seamless health information exchange;
- (b) establish registries, in consultation with other statutory authorities, at appropriate levels to create single source of truth in respect of clients, health facilities, healthcare providers, health products and technologies;
- (c) promote adoption of best practices and standards for digital health that facilitate data exchange;
- (d) establish a system of shareable and portable personal health records, based on best practices and standards;
- (e) ensure health data portability;
- (f) facilitate collection and analysis of data to inform policy and research in the health sector;
- (g) promote the development of enterprise-class health application systems;
- (h) strengthen existing health information systems by ensuring their conformity with the prescribed standards and integration with the comprehensive integrated health information system;
- (i) develop and implement the infrastructure for health data exchange of health information in a secured manner;
- (j) maintain, in collaboration with the counties and

other statutory authorities, the technological infrastructure necessary for the core digital health services;

- (k) support the development and implementation of standards for enhanced interoperability;
- (l) undertake resource mobilization for implementation of health digitization in the country;
- (m) certify digital health solutions based on best practices and standards;
- (n) advise the Cabinet Secretary on matters related to digital health; and
- (o) perform any other function for the better carrying out of functions under this Act.

7. (1) The Board shall be responsible for the management and administration of the Agency.

Powers of the Agency.

(2) Without prejudice to the generality of the foregoing, the Agency shall have power to—

- (a) manage, control and administer the assets of the Agency in such manner and for such purpose as best promotes the objects for which the Agency is established in accordance with the Public Procurement and Assets Disposal Act, 2022:

No. 33 of 2015.

Provided that the Agency shall not charge or dispose of any immovable property without the prior approval of the National Assembly;

- (b) enter into association with such other bodies or organizations, within or outside Kenya, as it may consider desirable or appropriate and in furtherance of the purpose for which the Agency is established; and
- (c) invest the funds of the Agency not immediately required for its purposes in the manner provided in this Act.

8. (1) There shall be a Board of Directors of the Agency which shall consist of—

Board of Directors.

- (a) a non-executive chairperson who shall be

appointed by the President;

- (b) the Principal Secretary responsible for Health or a representative designated in writing;
- (c) the Principal Secretary responsible for National Treasury or a representative designated in writing;
- (d) the Principal Secretary responsible for Information, Communication and Technology or a representative designated in writing;
- (e) the Data Commissioner or a representative designated in writing;
- (f) one person representing the private sector appointed by the Cabinet Secretary;
- (g) three persons, not being Governors, nominated by the Council of County Governors with knowledge and experience in matters of digital health; and
- (h) the Chief Executive Officer, who shall be an *ex-officio* member of the Board.

(2) The Chairperson of the Board and the members appointed under subsection (1) (f) and (g) shall serve for a term of three years and shall be eligible for re-appointment for one further term of three years.

(3) In appointing persons as members of the Board under subsection (1)(f) and (g), the Cabinet Secretary shall ensure that the appointments afford equal opportunity to men and women, youth, persons with disabilities, minorities and marginalized groups and ensure regional balance.

(4) A person appointed to the Board under sub-section (1)(a), (f) and (g) shall cease to be a member of the Board if the person—

- (a) resigns in writing addressed to the Cabinet Secretary;
- (b) is adjudged bankrupt;
- (c) is absent from three consecutive meetings without the permission of the Chairperson;
- (d) is convicted of a criminal offence and sentenced to imprisonment for a term exceeding six months; or
- (e) is unable to perform the functions of his office by

reason of mental or physical infirmity.

(5) Despite subsection (4), the Chairperson or the member of the Board may be removed for –

- (a) incompetence or neglect of duty;
- (b) gross misconduct whether in the performance of the members' functions or otherwise; or
- (c) violation of the Constitution or any other written law.

(6) The Agency shall pay to the directors such remuneration, fees or allowances for expenses as may be determined by the Cabinet Secretary on the advice of the Salaries and Remuneration Commission.

(7) The Board may co-opt any other person with necessary expertise as it may deem necessary to assist the Board in discharging its duties and responsibilities.

9. Except as provided in the Schedule, the Board shall regulate its own procedure.

Conduct of business and affairs of the Board. Committees of the Board.

10. (1) The Board may, from time to time, establish such committees as it considers necessary for the better carrying out of its functions under this Act.

(2) The Board may co-opt into the membership of a committee established under sub-section (1) such other person whose knowledge and skills are found necessary for the functions of the Agency.

11. (1) The Board shall, through an open, transparent and competitive recruitment process, appoint a suitably qualified person to be the Chief Executive Officer of the Agency.

Chief Executive Officer.

(2) Subject to this Act, the Chief Executive Officer shall be appointed on such terms and conditions of service as shall be determined by the Board in the instrument of appointment or otherwise in writing from time to time in consultation with the Salaries and Remuneration Commission.

12. (1) A person shall be qualified for appointment as the Chief Executive Officer of the Agency if that person—

Qualification for appointment as Chief Executive Officer.

- (a) has a minimum of a master's degree from a

university recognized in Kenya;

- (b) has at least ten years' knowledge and experience in health information science, data science, data governance, health informatics, digital health or any other relevant field;
- (c) has served in a management level for a period of at least five years;
- (d) has not been convicted of an offence and is not serving a term of imprisonment; and
- (e) meets the requirements of Chapter Six of the Constitution.

(2) The Chief Executive Officer shall, subject to the directions of the Board, be responsible for the day to day management of the affairs and staff of the Board.

(3) The Chief Executive Officer shall be the accounting officer of the Agency.

(4) The Chief Executive Officer shall hold office for a period of three years and shall be eligible for re-appointment for one further term of three years.

**13.** (1) There shall be a Corporation Secretary who shall be competitively recruited and appointed by the Board on such terms as the Board may, on the advice of the Salaries and Remuneration Commission, determine.

Corporation  
Secretary.

(2) A person qualifies for appointment as the Corporation Secretary of the Agency if the person—

- (a) holds a bachelor's degree in law from a university recognized in Kenya;
- (b) is an Advocate of the High Court of Kenya;
- (c) has at least five years' experience as a corporation secretary or a similar governance role;
- (d) is a member in good standing of the Institute of Certified Secretaries of Kenya; and
- (e) meets the requirements of Chapter Six of the Constitution.

(3) The Corporation Secretary shall be the Secretary to

the Board and shall—

- (a) in consultation with the Chairperson of the Board, issue notices for meetings of the Board;
- (b) keep in custody, the records of the deliberations, decisions, and resolutions of the Board;
- (c) transmit decisions and resolutions of the Board to the Chief Executive Officer for execution, implementation and other relevant action;
- (d) provide guidance to the Board on their duties and responsibilities on matters relating to governance; and
- (e) perform such other duties as the Board may direct.

14. The Board may appoint such staff as may be necessary for the proper discharge of the functions of the Agency under this Act, upon such terms and conditions of service as the Board may determine upon the advice of the Salaries and Remuneration Commission.

Staff.

**PART III—THE ESTABLISHMENT AND  
ADMINISTRATION OF THE COMPREHENSIVE  
INTEGRATED HEALTH INFORMATION SYSTEM**

15. (1) There is established a system to be known as the comprehensive integrated health information system which shall be administered by the Agency.

Establishment of an integrated health information system.

(2) The Agency shall, in consultation with the Cabinet Secretary, establish a framework for administration and management of the system and shall ensure the maintenance of the integrity and security of the system.

(3) The system shall operate as a point of collection, collation, analysis, reporting, storage, usage, sharing, retrieval or archival of data related to the state of physical or mental health of the 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.

**16.** The system shall comprise of —

Components of  
the System.

- (a) an Information and Communication Technology environment which consists of the underlying infrastructure, enterprise service bus, standards, data banks, data exchange, governance, actors and applications, internet enabled environment, and other related components;
- (b) data collection, collation, analysis, reporting, storage, usage, sharing, retrieval, or archival;
- (c) applications, infrastructure and tools, and best practices that enable access to and analysis of information to improve and optimise decisions and performance;
- (d) data quality assurance and audit; and
- (e) shared or common resources, including the 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.

**17.** The main objectives of the system shall be to—

Objectives of the  
system.

- (a) facilitate people-centred 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 and use;

- (f) serve the health sector and facilitate in a progressive and equitable manner realisation of universal health coverage, to achieve the highest attainable standard of health;
- (g) ensure standardisation of health data management; and
- (h) facilitate the tracking and tracing of health products and technologies in the country.

**18.** (1) The Agency shall adopt relevant internationally accepted standards, procedures, technical details, best practices, and formalities for effective implementation of the system.

Technical aspect of the system.

(2) The processes and technical aspects of the system shall be guided by the following principles—

- (a) confidentiality, security and privacy;
- (b) scalability and interoperability;
- (c) accuracy, responsiveness and reliability;
- (d) efficiency and effectiveness;
- (e) redundancy;
- (f) transparency;
- (g) simplicity and accessibility; and
- (h) consistency in use.

#### **PART IV— HEALTH DATA GOVERNANCE**

**19.** For the purposes of this Act, health data shall be classified into the following categories—

Classification of health data.

- (a) sensitive personal level health data;
- (b) de-identified, pseudo-anonymized or anonymized individual-level health data;
- (c) administrative data;
- (d) aggregate health data;
- (e) medical equipment data; and
- (f) research for health data.

**20.** (1) Health data shall be governed by the following

Governing principles.

principles—

- (a) improvement of client health, safeguard of individuals and communities against harm and violations;
- (b) data security throughout the entire data life-cycle;
- (c) equity and accountability;
- (d) privacy and confidentiality; and
- (e) accuracy and reliability.

**21.** (1) The Cabinet Secretary shall, in consultation with the Director-General, establish a health data governance framework.

Establishment of health data governance framework.

(2) Without prejudice to the generality of subsection (1) the Cabinet Secretary shall—

- (a) develop guidelines to promote effective use of legacy data including data migration;
- (b) establish standards for integration, interoperability and exchange of health data;
- (c) ensure regular update and availability of the national health data dictionary for utilization within the system;
- (d) establish standards for and conduct routine data quality checks in the system;
- (e) ensure the security and accountability of data for the system while promoting appropriate data use and sharing;
- (f) provide guidance on the integration and interoperability of all health information systems into the system per set standards; and
- (g) require all health data controllers and processors to report designated health data in accordance with ministry of health in the approved and prescribed formats and platforms.

**22.** The Agency shall be the custodian for all health data in Kenya.

Health data custodian.

23. (1) The Cabinet Secretary shall ensure that Health data is used for public good.

Health data use.

(2) The Agency shall provide health data to the Cabinet Secretary for relevant action.

#### **PART V—CONFIDENTIALITY, PRIVACY AND SECURITY OF DATA**

24. (1) The Cabinet Secretary shall be responsible for the confidentiality, privacy and security of all sensitive personal data held in the system.

Security, privacy and disclosure of data in the system.

(2) Sensitive personal data held in the system shall not be disclosed to a third party unless—

- (a) the data subject is unable to give informed consent for the disclosure and such consent is given by a person authorised by the data subject in writing to grant consent;
- (b) the disclosure has been authorised by the implementation of written law or the enforcement of a court order;
- (c) a health service without informed consent as authorised by written law or court order is being provided;
- (d) the data subject is being treated in an emergency situation;
- (e) failure to treat the data subject, or a group of people which includes the data subject, would result in a serious risk to public health; or
- (f) a delay in providing a health service to the data subject may result in death or irreversible damage to the health of the data subject and the data subject has not expressly, by implication or by conduct refused that service.

(3) The Cabinet Secretary shall be responsible for the privacy of the data held in the system during all the data life cycle stages.

(4) Where the data held in the system data is intended to be used for research and planning, the Cabinet Secretary shall be the data controller for the purposes of section 53 of

No. 29 of 2019.

the Data Protection Act, 2019.

(5) The Cabinet Secretary shall establish the security measures in the system to protect sensitive personal data including—

- (a) personalised authentication and log-in credentials;
- (b) role based user rights;
- (c) audit trails for all activities within the system;
- (d) digital and physical security of the system; and
- (e) an encrypted backup that is subject to the security measures herein.

**25.** (1) Data held in the system shall be maintained for a minimum period of twenty years.

Retention and disposal of data in system.

(2) Data held in the system may be maintained for a period exceeding that specified in subsection (1) where—

- (a) it is required or authorised by law;
- (b) it is authorised by the data subject; or
- (c) it is reasonably necessary for a lawful purpose;
- (d) for historical, statistical or research purposes.

(3) Where the period for the maintenance of the data held in the system is not extended under subsection (2), the data shall be secured by de-identification, anonymization, pseudo-anonymization or archiving, or establishing such technical and organisational security measures as the Cabinet Secretary may determine to be necessary.

**26.** (1) The Cabinet Secretary shall—

Establishment of health data banks.

- (a) establish a national health data bank and designate county health data banks;
  - (b) store the health data submitted to the system in the national health data bank; and
  - (c) establish seamless integration and interoperability of the national health data bank with other relevant databases.
- (2) The County Executive Committee Member shall—
- (a) establish county health data banks;

- (b) store the health data submitted to the system in the county health data bank; and
- (c) establish seamless integration and interoperability of the county health data bank with other relevant databases and data banks.

(3) The health information databases and data banks referred to in subsections (1) and (2) shall be established at the different levels of healthcare delivery specified under section 25 of the Health Act, 2017.

No. 21 of 2017.

(4) A data controller shall transmit health data containing sensitive personal data to the national health information data bank and county health information data bank in a secure and encrypted form.

(5) A data controller shall maintain records of the health data containing sensitive personal data transmitted to the national health information data bank and county health information data bank under subsection (4).

27. The health data that is contained in a health data bank shall be applied to—

Use of sensitive personal data.

- (a) identify a person who needs or is receiving a health service;
- (b) provide health services to, or facilitate the care of or treatment of, a person;
- (c) identify a health service provider who is providing a health service;
- (d) identify a person offering health insurance;
- (e) assess and address public health needs;
- (f) conduct disease surveillance, research and innovation;
- (g) engage in health system planning, management, evaluation or improvement, including health service development, management, delivery, monitoring and evaluation including surveys;
- (h) assess the safety and effectiveness of health services; and
- (i) continuous enhancement of the system.

**28.** The responsibility of the data controller of a health data bank shall be to—

Responsibilities of health data bank controller.

- (a) take reasonable measures to ensure that no agent or the data controller or processor collects, uses, discloses, retains or disposes of sensitive personal data unless it is in accordance with the law; and
- (b) remain responsible for any sensitive personal data that is collected, used, disclosed, retained or disposed of by the data controller's or processor's agents, regardless of whether or not the collection, use, disclosure, retention or disposal was carried out in accordance with this Act or other law.

**29.** A person authorised by the data controller to enter sensitive personal data into the system shall ensure compliance with section 30(2) of this Act.

Request for information by authorized person.

**30.** (1) A data controller may disclose sensitive personal data about a person who is deceased, or is reasonably suspected to be deceased when—

Disclosure of sensitive personal data of deceased persons.

- (a) identifying the person;
- (b) informing a person to whom it is reasonable to inform in the circumstances of; or
- (c) investigating the cause of death.

(2) A request under subsection (1) shall be made as provided under the relevant law.

**31.** (1) A healthcare provider shall ensure that he or she has obtained consent to process sensitive personal data.

Consent.

(2) Subsection (1) shall not apply where a health service is being provided—

- (a) for public health in accordance with the Public Health Act; and
- (b) in compliance with any other statutory requirements.

(3) When processing personal data, a healthcare provider shall—

- (a) ensure confidentiality of the information of the client;
- (b) provide prompt and accurate data necessary for

treatment of the patient;

- (c) comply with the duty to notify the data subject in accordance with the Data Protection Act, 2019;

No. 24 of 2019.

(4) A data subject who has issued a consent to the use or disclosure of personal data may withdraw their consent at any time by notifying the health care provider.

**32.** Where a data subject is a minor or for any other reason does not have the capacity to issue informed written consent, the parent, an appointed guardian or next friend of the patient shall, for purposes of subsection (1), act on behalf of, and in the best interest of, the patient in accordance with the law.

Processing of personal data relating to a minor or a person without capacity.

**33.** (1) A data controller shall protect sensitive personal data and adopt reasonable administrative, technical and physical safeguards to ensure the privacy, confidentiality, security, accuracy and integrity of the data.

Duty to protect sensitive personal data.

(2) A data controller shall establish controls that govern persons who may use sensitive personal data and such data shall not be used unless—

- (a) the identity of the person seeking to use the information is verified;
- (b) the data processor is authorized to use it, and
- (c) the proposed use is authorised under this Act.

**34.** The Cabinet Secretary shall develop regulations for the disposal of sensitive personal data.

Disposal of health information.

**35.** (1) A person commits an offence if, in relation to health data, the person—

Breach of health data.

- (a) tampers with the data;
- (b) abuses a privilege;
- (c) discloses inauthentic access to the data;
- (d) improperly disposes of unnecessary but sensitive data;
- (e) loses data;
- (f) steals data; or
- (g) shares sensitive personal data to an unauthorised

party.

(2) A person who commits an offence under subsection (1) shall be liable, on conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding fifteen years, or to both.

(3) Where a person commits an offence under subsection (1) with respect to sensitive personal data, that person shall be liable, on conviction, to the penalties under section 73 of the Data Protection Act, 2019.

No. 24 of 2019.

**36.** (1) Subject to this Act, a person has a right, on request, to examine and receive a copy of his or her personal health information maintained by a data controller.

Health Data  
Portability.

(2) A request under subsection (1) shall be made in writing to the relevant health facility or health information bank.

(3) The health data controller shall comply with the provisions of section 38 of the Data Protection Act in enabling access and portability of personal health records.

No. 24 of 2019.

**37.** A person in charge of a health data bank may refuse to grant access to a third party, all or part of a person's sensitive data or health information if it is reasonable to believe that—

Refusal to grant  
access to sensitive  
personal data.

- (a) access is restricted by a court process, order or judgement;
- (b) another law prohibits disclosure;
- (c) the information was collected or created in the course of an inspection, investigation or similar procedure not yet concluded;
- (d) access may lead to the identification of a person who provided information in the record to the custodian in circumstances in which confidentiality was expected; or
- (e) access may result in the release of another person's personal health data.

**38.** (1) A health data bank and health data controller, before releasing any personal health data to any person, shall—

Precautions on  
release of  
sensitive personal  
health data.

- (a) be satisfied as to the identity of the person making the request; and
  - (b) take reasonable steps to ensure that any personal health information intended for a person is received only by that person or—
    - (i) where the data subject is a minor, by a person who has parental authority or by a guardian;
    - (ii) where the data subject has a mental or other disability, by a person duly authorised to act as their guardian or administrator; or
    - (iii) in any other case, by a person duly authorised by the data subject or by a court order.
- (2) A health data controller shall not disclose, for the purpose of market research, personal health information that is contained in a health data information bank.

**39.** A health data bank or a health provider may, upon request by the data subject—

Right to rectification or erasure.

- (a) rectify, without undue delay, personal data in its possession or under its control that is inaccurate, outdated, incomplete or misleading; or
- (b) erase or destroy, without undue delay, personal data that the health data bank or health provider is no longer authorised to retain, or personal data which is irrelevant, excessive or obtained unlawfully.

#### **PART VI—E-HEALTH SERVICE DELIVERY**

**40.** (1) E-Health shall be a recognized model of health service delivery.

e-Health as a mode of health service delivery.

(2) E-Health Services shall be complementary to existing healthcare service delivery modalities.

**41.** (1) The e-Health service shall be provided through—

Provision of e-Health services.

- (a) telemedicine;
- (b) electronic health records;
- (c) m-health;

- (d) e-learning;
- (e) telehealth; and
- (f) any other recognized e-health service.

(2) An entity providing e-health services shall be—

- (a) a healthcare provider holding a valid licence issued by a relevant regulatory body;
- (b) a healthcare provider holding a valid licence from an equivalent regulatory authority outside Kenya but shall be recognized by the local regulatory authority;
- (c) a health facility licenced to offer e-health services by the relevant regulatory body; or
- (d) for foreign facilities, be licenced by an equivalent regulatory authority recognized in Kenya.

(3) The Cabinet Secretary shall develop standards and guidelines for the e-Health platform.

**42.** (1) The e-Health service shall be an integral part of health service delivery to benefit people in a manner that is ethical, safe, secure, reliable, equitable and sustainable.

Principles and objectives of e-Health.

(2) The objectives of e-Health shall be to—

- (a) promote patient-centred health care services;
- (b) ensure equitable access to quality health care services using Information and Communication Technology;
- (c) promote the integration of e-health into the healthcare system;
- (d) facilitate the integration of e-health solutions; and
- (e) promote the use of e-health solutions.

**43.** (1) In the provision of e-health services to a client, a healthcare provider shall—

E-health services.

- (a) provide the client with all the information for the management of his or her health;
- (b) ensure the client can access their own health records where necessary;

- (c) ensure the client's data is managed as prescribed in the law;
- (d) ensure the highest possible quality of care is delivered;
- (e) ensure that the agents of the e-health service provider adhere to the provisions of this Act;
- (f) ensure the platform used is interoperable with the system;
- (g) ensure that when e-health service delivery involves a minor, the consent of the parent or an appointed guardian shall be obtained; and
- (h) ensure that when e-health service delivery involves a mentally ill person, the consent of an appointed guardian or next friend of the patient is obtained.

(2) The use of e- health service platforms to share the information of a patient including images and lab results for consultation and training shall adhere to the standards prescribed by law.

44. In the delivery of e-health services, it shall be the responsibility of the e-health service provider to meet their reporting obligations in accordance with the provisions of this Act.

Reporting.

#### PART VII— E-WASTE MANAGEMENT

45. (1) The Cabinet Secretary shall—

E-waste management.

- (a) in consultation with county governments and relevant lead agencies, develop guidelines for the safe handling and disposal of all health sector related e-waste material; and
- (b) in consultation with relevant stakeholders, develop an e-waste management system for the health sector.

(2) The e-waste management system referred to in subsection (1) above, shall—

- (a) comprise an appropriate mechanism for segregation of e-waste at source, collection, transportation and processing;
- (b) promote reuse and lifetime extension;

- (c) promote activities aimed at resource recovery and recycling of e-waste materials into useful products;
- (d) embrace the best available technologies and practices in e-waste management; and
- (e) promote sustainable models for e-waste management through public-private partnerships.

#### **PART VIII—HEALTH TOURISM**

46. (1) The Cabinet Secretary shall take all necessary measures to safeguard the transfer of a client's medical records to and from facilities outside Kenya.

Development of guidelines on health tourism.

(2) A data controller, who being a custodian of, and who transfers outside Kenya, biological specimens, health images, human tissues and organs of a Kenyan citizen shall ensure confidentiality of personal health information:

Provided that where such transfer is for purposes of health research or post-mortem, the Data controller shall—

- (a) provide a report to the Director-General for Health stating the findings;
- (b) not share the health information without notifying the Cabinet Secretary; and
- (c) seek guidance from the Cabinet Secretary in the manner the health information shall be stored, processed and destroyed.”

(3) The Cabinet Secretary shall in consultation with the County Governments, and relevant lead agencies, develop guidelines on health tourism.

47. Personal health information may only be shared to any person outside Kenya for the purposes of health tourism.

Disclosure of sensitive personal data to organizations outside Kenya.

#### **PART IX—FINANCIAL PROVISIONS**

48. (1) The funds of the Agency shall consist of—

Funds of the Agency.

- (a) monies appropriated by the National Assembly for the purposes of the Agency;
- (b) such monies or assets as may accrue to the Agency in the course of the exercise of its powers or in the performance of its functions under this Act;
- (c) such levy fees for services rendered by the

Agency;

- (d) monies from any other source provided, donated, lent or given as a grant to the Agency; and
- (e) any other funds designated for or accruing to the Agency by virtue of the operation of law.

(2) There shall be paid out of the funds of the Agency, all expenditure incurred, administrative expenses or for such other purposes as may be necessary for the discharge of the functions of the Agency in the exercise of its powers or the performance of its functions under this Act.

**49.** The financial year of the Agency shall be the period of twelve months ending on the thirtieth day of June in each year.

Financial year.

**50.** (1) Before the commencement of each financial year, the Chief Executive Officer shall cause to be prepared estimates of the revenue and expenditure of the Agency for that year.

Annual estimates.

(2) The annual estimates shall make provision for all the estimated expenditure of the Agency for the financial year concerned and in particular shall provide for—

- (a) payment of salaries, allowances, gratuities, pensions and other charges in respect of the members of the Board and Agency;
- (b) maintenance of buildings and grounds of the Agency; and
- (c) funding of training, research and development of activities in relation to the organization and functioning of the Agency.

(3) The annual estimates shall be approved by the Board before the commencement of the financial year to which they relate, and shall be submitted by the Chief Executive Officer for tabling in the National Assembly.

(4) The annual estimates, once approved by the Board, shall not be amended before being tabled in the National Assembly.

(5) No expenditure shall be incurred for the purposes of the Agency except in accordance with the annual estimates approved under subsection (3).

51. (1) The Board shall cause to be kept all proper audit books and records of accounts of the income, expenditure, assets and liabilities of the Agency.

Accounts and  
audit.

(2) The accounts of the Agency shall be audited and reported upon in accordance with the Public Finance Management Act, 2012 and the Public Audit Act, 2015.

52. (1) At the end of each financial year, the Chief Executive Officer shall prepare an annual report on the activities of Agency.

Annual report.

(2) The annual report shall be submitted for tabling in the National Assembly not later than one month after the submission of the Auditor-General's report.

(3) The annual report shall contain—

- (a) the financial statements of the Agency;
- (b) a description of the activities and outcomes of functioning of the Agency; and
- (c) any other information that the Agency may consider relevant.

53. The Chief Executive Officer may, in accordance with the law relating to the management of public finance, open bank accounts on behalf of the Agency with the approval of the Board and the National Treasury and shall, as the accounting officer, be responsible for the proper management of the finances of the Agency.

Bank account.

54. (1) All monies in the Agency which are not immediately required to be applied for the purposes of this Act shall be invested—

Investment of  
Funds.

- (a) in such investment in a reputable bank on the advice of the Central Bank of Kenya, being an investment in which trust funds, or part thereof, are authorized by law to be invested; and
- (b) in government securities as may be approved by the National Treasury.

(2) All investments made under this section shall be held in the name of the Agency.

#### **PART X—MISCELLANEOUS PROVISIONS**

55. No matter or thing done by the Chairperson, a Board member, or any officer, employee or agent of the

Protection from  
personal liability.

Agency shall, if the matter or thing is done in good faith and for the purposes of executing any provisions of this Act, render the Chairperson, Board member, or any officer, employee or agent of the Agency or any person acting under the direction of those persons personally liable for any action, claim or demand arising from the same.

**56.** (1) The Chairperson or a member of the Board, who has a direct or indirect personal interest in a matter being considered or to be considered by the Board, shall as soon as reasonably practicable after the relevant facts concerning the matter have come to their knowledge, disclose the nature of such interest.

Conflict of interest.

(2) A disclosure of interest made under subsection (1) shall be recorded in the minutes of the meeting and the chairperson or member shall not take part in the consideration or discussion on or vote during any deliberations on the matter.

(3) A person who fails to make the requisite disclosure under this section commits an offence.

(4) A member of the Board shall recuse themselves from proceedings before the Board in which they have apparent or perceived conflict of interest.

**57.** (1) A member of the Board or staff of the Agency may not without the consent in writing given by, or on behalf of, the Board, publish or disclose to any person other than in the course of the person's duties, the contents of any document, communication or information which relates to, and which has come to the person's knowledge in the course of the person's duties under this Act.

Confidentiality.

(2) The limitation on disclosure referred to under subsection (1) shall not be construed to prevent the disclosure of criminal activity by a member of the Board or staff of the Agency.

**58.** A person responsible for a matter in question before the Board shall co-operate with the Board and shall in particular—

Duty to cooperate.

- (a) respond to any inquiry made by the Board;
- (b) furnish the Board with a report in respect of the

question raised; and

- (c) provide any other information that the Board may require in the performance of its functions under the Constitution, this Act or in any other written law.

**59.** (1) A person who—

Offences.

- (a) obstructs, hinders or threatens a member, an officer, employee or agent of the Board acting under this Act;
- (b) disregards an order of the Board;
- (c) submits false or misleading information to the Board; or
- (d) makes a false representation to, or knowingly misleads a member, an officer, employee or agent of Board acting under this Act,

commits an offence and is liable, on conviction, to a fine of not less than one million shillings or to imprisonment for a term of not less than two years, or to both.

(2) Any person who violates or fails to comply with any provision of this Act for which no other penalty is provided, commits an offence, and is liable on conviction to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

**60.** The Cabinet Secretary may, in consultation with the Agency and the county governments, develop regulations providing for —

Regulations.

- (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
- (d) the establishment and implementation of the data exchange component as per the Kenya Health

Enterprise Architecture.

**61.** Any person processing personal data under this Act shall comply with the Data Protection Act, 2019.

Compliance to the Data Protection Act, 2019.

**62.** A person, who being a data controller or data processor of health data or who has been handling health information before the commencement of this Act, shall, within six months of the commencement of this Act, comply with the requirements of this Act.

Transitional provision.

**SCHEDULE**

(s.9)

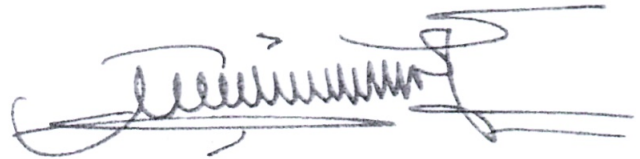
**CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD**

- |  |   |
|--|---|
| <p>1. The Board shall meet as often as may be necessary for the dispatch of its business but there shall be at least four meetings of the Board in any financial year.</p>   | <p>Meetings.</p>  |
| <p>2. At the first meeting, the Board elects a vice-chairperson amongst their number who shall be a person of opposite gender.</p>   | <p>Election of vice-chairperson.</p>                            |
| <p>3. A meeting of the Board shall be held on such date and at such time and place as the Board may determine.</p>   | <p>Time and place of meetings.</p>                              |
| <p>4. The chairperson shall, on the written application of one-third of the members, convene a special meeting of the Board.</p>   | <p>Special meetings.</p>  |
| <p>5. The quorum for the conduct of business at a meeting of the Board shall be the chairperson and any four members.</p>  | <p>Quorum.</p>  |
| <p>6. The Chairperson shall preside at every meeting of the Board at which the chairperson shall be present and in the absence of the chairperson at a meeting, the vice-chairperson shall preside and in the absence of both the chairperson and the vice-chairperson, the members present shall elect one of their number who has, with respect to that meeting and the business transacted thereat, have all the powers of the chairperson.</p> | <p>Voting.</p>  |
| <p>7. Unless a unanimous decision is reached, a decision on any matter before the Board shall be by concurrence of a majority of all the members present and voting at the meeting.</p>  | <p>Decisions of the Board.</p>                                  |
| <p>8. Subject to paragraph 5, no proceedings of the Board shall be invalid by reason only of a vacancy among the members thereof.</p>  | <p>Vacancy.</p>   |
| <p>9. Unless otherwise provided by or under any law, all instruments made by and decisions of the Board shall be signified under the hand of the Chairperson.</p>  | <p>Signification of instruments and decisions of the Board.</p> |

*The Digital Health Bill, 2023*

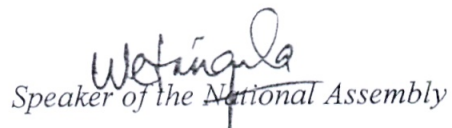
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I certify that this printed impression is a true copy of the Bill passed by the National Assembly on the 27<sup>th</sup> September, 2023.



*Clerk of the National Assembly*

Endorsed for presentation to the Senate in accordance with the provisions of Standing Order 142 of the National Assembly Standing Orders.



*Speaker of the National Assembly*

---

ya Ports Authority (KPA) has allocated Sh1.6 billion for the project.

rehabilitation of Kendu Bay pier on September 30  
GEORGE ODIWUOR I NATION

## REPUBLIC OF KENYA



### THIRTEENTH PARLIAMENT | SECOND SESSION THE SENATE

#### INVITATION FOR SUBMISSION OF MEMORANDA

At a sitting of the Senate held on Tuesday, 3<sup>rd</sup> October, 2023, the **Digital Health Bill (National Assembly Bills No. 57 of 2023)** and the **Social Health Insurance Bill (National Assembly Bills No. 58 of 2023)** were introduced in the Senate by way of First Reading and thereafter stood committed to the Standing Committee on Health.

Pursuant to the provisions of Article 118 of the Constitution and Standing Order 145 [5] of the Senate Standing Orders, the Standing Committee on Health now invites interested members of the public to submit any representations that they may have on the Bills.

The representations may be made by way of written memoranda submitted to the Clerk of the Senate on the address [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke) and copied to [healthcommittee.senate@parliament.go.ke](mailto:healthcommittee.senate@parliament.go.ke) to be received on or before **Saturday, 7<sup>th</sup> October, 2023 at 5.00 p.m.**

The Bills may be accessed on the Parliament website at <http://www.parliament.go.ke/the-senate/house-business/bills>.

**J.M. NYEGENYE, CBS,  
CLERK OF THE SENATE.**

Yours

REPUBLIC OF KENYA



Telegraphic Address  
'Bunge', Nairobi  
Telephone 2848000  
Fax: 2243694  
E-mail: [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke)

**Annex 4**

The Senate  
Clerk's Chambers  
Parliament Buildings  
P. O. Box 41842 -00100  
NAIROBI, Kenya

PARLIAMENT  
OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/163/09/2023

4<sup>th</sup> October, 2023

**Dr. Brian Lishenga, MBChB, MSc, MFMED,**  
Chairperson,  
Rural Private Hospitals Association,  
P. O. Box 4982-00200,  
**NAIROBI.**

Dear *Seni*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

The Standing Committee on Health is established pursuant to standing order 228 (3) of the Senate Standing Orders and is mandated to consider all matters relating to medical services, public health and sanitation.

At the sitting of the Senate held on Tuesday, 3<sup>rd</sup> October, 2023, the Digital Health Bill (National Assembly Bills No. 57 of 2023) and the Social Health Insurance Bill (National Assembly Bills No. 58 of 2023) were introduced in the Senate by way of First Reading and thereafter stood committed to the Standing Committee on Health.

Pursuant to the provisions of Article 118 of the Constitution and Standing Order 145 (5) of the Senate Standing Orders, the Committee hereby invites you to -

- a) Submit your written memoranda to the Clerk of the Senate on the address [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke) and copied to the Standing Committee on Health on the address [healthcommittee.senate@parliament.go.ke](mailto:healthcommittee.senate@parliament.go.ke) on or before **Friday, 6<sup>th</sup> October, 2023** at 8.00 a.m.; and
- b) Appear before the Committee on **Friday, 6<sup>th</sup> October, 2023** at **10.00 a.m.** at the **Senate Chamber, Main Parliament Buildings** to deliberate on your submissions.

The Bill may also be accessed on the Parliament Website at <http://www.parliament.go.ke/the-senate/house-business/bills>

**Dr. Christine Sagini, Senior Clerk Assistant (Cell Number: 0725-052269; Email [christine.sagini@parliament.go.ke](mailto:christine.sagini@parliament.go.ke)),** is the Clerk to the Committee and is responsible for all arrangements relating to this matter.

Yours

*Sincerely*  
*[Signature]*

**J.M. NYEGENYE, CBS,**  
**CLERK OF THE SENATE.**

Annex 4

REPUBLIC OF KENYA

Telegraphic Address

'Bunge', Nairobi

Telephone 2848000

Fax: 2243694

E-mail: [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke)



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NAIROBI, Kenya

PARLIAMENT

OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/157/09/2023

4<sup>th</sup> October, 2023

Hon. Anne Waiguru, EGH, OGW,

Chairperson,

Council of Governors,

Delta Corner,

P.O Box 40401 - 00100

NAIROBI.

Dear *Governor*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

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Yours

*Sincerely*  
*J.M. Nyegenye*

J.M. NYEGENYE, CBS,

CLERK OF THE SENATE.

REPUBLIC OF KENYA

Telegraphic Address  
'Bunge', Nairobi  
Telephone 2848000  
Fax: 2243694  
E-mail: [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke)



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NAIROBI, Kenya

PARLIAMENT  
OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/160/09/2023

4<sup>th</sup> October, 2023

**Mr. Godfrey Kiptum,**  
Chief Executive Officer &  
Commissioner of Insurance,  
Insurance Regulatory Authority,  
P. O. Box 43505-00100,  
**NAIROBI.**

Dear *Seny*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL  
(NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH  
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Yours

*J.M. Nyegenye*  
**J.M. NYEGENYE, CBS,**  
**CLERK OF THE SENATE.**

REPUBLIC OF KENYA

Telegraphic Address

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Telephone 2848000

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E-mail: [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke)



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PARLIAMENT

OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/157/09/2023

4<sup>th</sup> October, 2023

**Ms. Susan Nakhumicha Wafula,**

Cabinet Secretary,

Ministry Of Health,

Afya House- Cathedral Road,

P.O BOX 30016-00100,

**NAIROBI.**

Dear *CS*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

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Yours

*Sincerely,*

  
J.M. NYEGENYE, CBS,  
CLERK OF THE SENATE.

Copy to -

**Mr. Harry Kimtai,**  
Principal Secretary,  
State Department for Medical Services,  
Afya House- Cathedral Road,  
P.O BOX 30016-00100,  
**NAIROBI.**

REPUBLIC OF KENYA



Telegraphic Address  
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OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/157/09/2023

4<sup>th</sup> October, 2023

~~Ms. Susan Nakhumicha Wafula,  
Cabinet Secretary,  
Ministry Of Health,  
Afya House- Cathedral Road,  
P.O BOX 30016-00100,  
NAIROBI.~~

Dear

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

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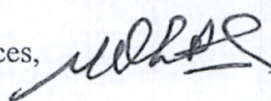
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Yours

✂ **J.M. NYEGENYE, CBS,  
CLERK OF THE SENATE.**

Copy to -

✓ **Mr. Harry Kimtai,**  
Principal Secretary,  
State Department for Medical Services,  
Afya House- Cathedral Road,  
P.O BOX 30016-00100,  
**NAIROBI.** 

REPUBLIC OF KENYA

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NAIROBI, Kenya

PARLIAMENT  
OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/159/09/2023

4<sup>th</sup> October, 2023

Dr. Francis Atwoli, CBS, EBS, MBS,  
Secretary General,  
Central Organization of Trade Unions,  
Solidarity Building, Digo Road,  
P.O Box 13000 – 00200  
**NAIROBI.**

Dear *Sir,*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

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*Sincerely,*

*J.M. Nyegenye*  
**J.M. NYEGENYE, CBS,  
CLERK OF THE SENATE.**

REPUBLIC OF KENYA

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NAIROBI, Kenya

PARLIAMENT  
OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCA/CORR/162/09/2023

4<sup>th</sup> October, 2023

Dr. Tim Theuri,  
Chief Executive Officer,  
Kenya Healthcare Federation,  
P. O. Box 37929-00100,  
**NAIROBI.**

Dear *Sm*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

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Dr. Christine Sagini, Senior Clerk Assistant (Cell Number: 0725-052269; Email [christine.sagini@parliament.go.ke](mailto:christine.sagini@parliament.go.ke)), is the Clerk to the Committee and is responsible for all arrangements relating to this matter.

Yours

*Sincerely*  
*J.M. NYEGENYE*  
J.M. NYEGENYE, CBS,  
CLERK OF THE SENATE.

REPUBLIC OF KENYA

Telegraphic Address  
'Bunge', Nairobi  
Telephone 2848000  
Fax: 2243694  
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The Senate  
Clerk's Chambers  
Parliament Buildings  
P. O. Box 41842 -00100  
NAIROBI, Kenya

PARLIAMENT  
OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/CORR/164/09/2023

4<sup>th</sup> October, 2023

**Dr. Samuel Mwenda,**  
Chairperson,  
Christian Health Association of Kenya,  
P. O. Box 30690 - 00100,  
**NAIROBI.**

Dear *Sam*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

The Standing Committee on Health is established pursuant to standing order 228 (3) of the Senate Standing Orders and is mandated to consider all matters relating to medical services, public health and sanitation.

At the sitting of the Senate held on Tuesday, 3<sup>rd</sup> October, 2023, the Digital Health Bill (National Assembly Bills No. 57 of 2023) and the Social Health Insurance Bill (National Assembly Bills No. 58 of 2023) were introduced in the Senate by way of First Reading and thereafter stood committed to the Standing Committee on Health.

Pursuant to the provisions of Article 118 of the Constitution and Standing Order 145 (5) of the Senate Standing Orders, the Committee hereby invites you to -

- a) Submit your written memoranda to the Clerk of the Senate on the address [clerk.senate@parliament.go.ke](mailto:clerk.senate@parliament.go.ke) and copied to the Standing Committee on Health on the address [healthcommittee.senate@parliament.go.ke](mailto:healthcommittee.senate@parliament.go.ke) on or before **Friday, 6<sup>th</sup> October, 2023** at 8.00 a.m.; and
- b) Appear before the Committee on **Friday, 6<sup>th</sup> October, 2023** at **10.00 a.m.** at the **Senate Chamber, Main Parliament Buildings** to deliberate on your submissions.

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OFFICE OF THE CLERK OF THE SENATE

Ref. SEN/DSEC/SCH/CORR/165/09/2023

4<sup>th</sup> October, 2023

**Dr. Samson Kuhora,**  
Ag. Chief Executive Officer,  
National Health Insurance Fund,  
P. O. Box 30443-00100,  
**NAIROBI.**

Dear *Sir,*

**RE: SUBMISSION OF MEMORANDA ON THE DIGITAL HEALTH BILL (NATIONAL ASSEMBLY BILLS NO. 57 OF 2023) AND THE SOCIAL HEALTH INSURANCE BILL (NATIONAL ASSEMBLY BILLS NO. 58 OF 2023)**

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Yours

*Sincerely,*  
*J.M. Nyegenye*

**J.M. NYEGENYE, CBS,**  
**CLERK OF THE SENATE.**

# Annex 5

REPUBLIC OF KENYA



PARLIAMENT OF KENYA

THE SENATE

Standing Committee on Health

13<sup>th</sup> Parliament | Second Session

## SCHEDULE FOR STAKEHOLDER ENGAGEMENT ON

### THE DIGITAL HEALTH BILL, 2023 AND THE SOCIAL HEALTH INSURANCE BILL, 2023

No.	ACTIVITY	DESCRIPTION	PROPOSED TIMELINES
1.	Advertisement for submission of written memoranda	1. Publish advertisement on: a) two newspapers with national distribution b) Parliament website c) Parliament social media pages	a) Newspaper Adverts - <b>Proposed date for publication:</b> Wednesday, 4 <sup>th</sup> October, 2023. - <b>Proposed deadline for submission of memoranda:</b> Saturday, 7 <sup>th</sup> October, 2023.
<b>A. Structured Stakeholder Engagement</b>			
2.	<i>Government Institutions</i>	- MOH - COG - NHIF - IRA	10.00 am Friday, 6 <sup>th</sup> October, 2023

2x30mA

3.	<i>Private Sector/ NGO</i>	- FKE - KHF - AKI - RUPHA - COTU	11.00 am	
4.		- IBP Kenya	12.00 noon	
5.	<i>Faith Based Organisation (FBO)</i>	- CHAK	1.00 pm	
<b>B. Bill Report</b>				
9.	<i>Consideration and adoption of:</i>	a) The Committee Report on Public Participation b) Committee Stage Amendments		Monday, 9 <sup>th</sup> October, 2023
11.	<i>Tabling of the Bill Report</i>			Wednesday, 11 <sup>th</sup> October, 2023

Annex 6

**Stakeholders**

1. Ministry of Health.
2. Council of Governors (CoG).
3. Insurance Regulatory Authority (IRA).
4. Federation of Kenya Employers (FKE).
5. International Budget Partnership Kenya (IBP Kenya).
6. Kenya Healthcare Federation (KHF).
7. Kenya Faith Based Health Services Consortium (FBOs) consisting—
  - a) Kenya Conference of Catholic Bishops (KCCB);
  - b) Christian Health Association of Kenya (CHAK);
  - c) Supreme Council of Kenya Muslims (SUPKEM); and
  - d) Mission for Essential Drugs and Supplies (MEDS).
8. Confraternity of Patients Kenya (COFPAK).
9. Association of Kenya Insurers (AKI).
10. Association of Kenya Medical Laboratory Scientific Officers (AKMLSO).
11. Health Records and Information Management Professionals comprising—
  - a) Health Records and Information Managers Board (Kenya); and
  - b) Association of Medical Records Officers (Kenya).
12. Kenya Union of Clinical Officers (KUCO).
13. Civil Society Organizations comprising—
  - a) Kenya AIDS NGOs Consortium (KANCO);
  - b) Amnesty International Kenya;
  - c) People's Health Movement (PHM); and
  - d) Institute of Public Finance (IPF).

**Annex**

- 14. Pharmaceutical Society of Kenya (PSK).
- 15. Kenya Dental Association (KDA).
- 16. Tech Hive Advisory Africa.
- 17. Helium Health Limited.

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
2	Federation of Kenya Employers	Amend the definition of the term “data commissioner” by inserting the words ‘as amended from time to time’ to read as follows— “data commissioner” means the person appointed under section 6 of the Data Protection Act, 2019 (as amended from time to time).	To ensure the reference is not rendered obsolete if the referenced Act is amended.	
	Insurance Regulatory Authority	Amend the definition of the term “health related data information” to include medical insurance data.	The definition as stated does not relate to health data information. The system established under the Bill is expected to contain all information that will be strategic to enable the government make decisions on universal health care. The information ought to include insurance data within the insurance sector as it will be important in pricing of health services to achieve universal health care.	
	Confraternity of Patients Kenya	Amend the definition of the term “health tourism” to state as follows—	The definition limits health tourism to medical treatment. Surgical, diagnostic and mental	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		<p>“health tourism” means a situation where a patient travels voluntarily across international borders to receive diagnostic, medical, surgical, dental and mental wellness treatment.</p>	<p>wellness has been excluded in the definition.</p>	
	<p>Kenya Healthcare Federation</p>	<p>Amend the definition of the term “consent” to adopt an interpretation that seeks to enhance opportunities including provision of reasonable accommodation for a person with a disability to make informed choices.</p>	<p>The Bill assigns meaning of consent as is assigned under the Data Protection Act 2019. The definition and exceptions for consent provided for in Data Protection Act 2019 deprive a person with a disability especially persons with intellectual and/or developmental disabilities from freely exercising their choice.</p> <p>The current interpretation of consent centers the guardian or caregiver of the Data subject in decision making process. Data Subject regardless of their disabilities or vulnerabilities should be at the center of decision-making process on issues affecting him or her. This addresses the issue of data privacy and confidentiality.</p>	
		<p>Amend the clause by inserting the definition of the term “data disaggregation” as follows—</p>	<p>Inclusion of Disaggregation of data will enhance the quality of reports and information generated by the healthcare systems and</p>	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		<p>“data disaggregation” means the presentation of numerical and non-numerical data broken down into detailed sub-categories and specific dimensions including age, sex and disability to illuminate underlying trends and patters in healthcare system.</p>	<p>actors which will aid in development of targeted intervention, policies and strategies as well as enhance data driven decision making process.</p>	
		<p>Amend the clause by replacing the definition of the term “digital health” to state—</p> <p>“digital health” refers to the use of information and communications technologies in medicine and other health professions to manage illnesses and health risks and to promote wellness.</p>	<p>Current meaning has room for misinterpretation and ambiguity and may need improvement.</p> <p>Review definition to the most acceptable and broad meanings of the compound words, ‘digital’ and ‘health’.</p> <p>Digital health, or digital healthcare, is a broad, multidisciplinary concept that includes concepts from an intersection between technology and healthcare. Digital health applies digital transformation to the healthcare field, incorporating software, hardware, and services. Under its umbrella, digital health includes mobile health (mHealth) apps, electronic health records (EHRs), electronic medical records (EMRs), wearable devices, telehealth and</p>	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
			telemedicine, as well as personalized medicine.	
		<p>Amend the clause by inserting the definition of the term “data disaggregation” as follows—</p> <p>“Stakeholders in Digital Health” include patients, practitioners, researchers, application developers, and medical device manufacturers and distributors.</p>	No rationale provided.	
		<p>Review and harmonize the definitions and relationships of the following terms—</p> <ul style="list-style-type: none"> <li>a) digital health;</li> <li>b) telehealth;</li> <li>c) telemedicine; and</li> <li>d) e-Health.</li> </ul> <p>Align with WHO guidelines and strategy.</p>	<p>Compare usage of terms in different jurisdictions, synonyms and interchangeability of definition of terms and usage.</p> <p>Definitions and meanings should be wide enough to include all the meanings of the concepts of telehealth such as teledentistry, teleradiology, telepharmacy, teleaudiology, teleneurology, telenursing telepalliative care, telepsychiatry telenutrition, teleneuropsychology telerehabilitation, teletrauma care, telecardiology, telepathology, teledermatology, teleophthalmology and telesurgery.</p>	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
	Kenya Dental Association	Amend the definition of the term “e-Health” to include telepharmacy.	Telepharmacy is one the critical components of Telemedicine or e-health.	
		Amend to include the definition of the term “telepharmacy” to state— “telepharmacy” refers to the use of telecommunications technology to facilitate or enable the delivery of high-quality pharmacy services in situations where the patient or healthcare team does not have direct (in-person) contact with pharmacy staff.	To complete the interpretation.	
3	International Budget Partnership Kenya	Amend the Bill to provide clarity and further to make provision for the place of county governments in view of the established Digital Health Agency.	Clause 3 (a) establishes the digital health agency as the custodian of data – a national body. A key concern is how will this enhance or hamper the effectiveness of counties in the provision of health services – a function largely devolved to counties in the COK, 2010. This raises other questions: What will be the access to information procedures for both National and County Governments? Will the	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
			<p>information be open to all counties for cross county learning or unique to every county?</p> <p>According to Clause 3b), the digital health agency is meant to establish and maintain a comprehensive integrated health information system, while clause 6b) mentions that the agency will maintain the comprehensive integrated management information system. These are two different things – one is a <i>integrated health information system</i> and the other is a <i>integrated management information system</i>. There is need for clarity around this. Further, how will the integrated system interlink with the existing systems e.g. KeHMIS, IHRIS, HRH, National Health Accounts etc?</p>	
	Kenya Dental Association	Amend clause 3(e) to include telepharmacy.	Telepharmacy is a critical component of telemedicine.	
6	International Budget Partnership Kenya	Amend the Bill to provide a standardised mechanism for financing the maintenance of data systems.	Clause 6(f) on functions of the Agency – The Agency shall facilitate collection and analysis of data to inform policy and research in the health sector. The bill in clause 25 classifies health	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
			<p>data, with one of the classifications being research for health data. The bill states that health data (personal health information) shall not be disclosed for the purpose of market research. (Clause 44(2)).</p> <p>The above raise a couple of questions: Who qualifies to access data for health research? Will access to the data come at a fee? This may be viewed from the perspective of the fee being charged to finance the maintenance of the data system but, on the contrary, it may result in unethical practices of 'selling data' unless the approach to how this is done is standardised.</p>	
8	Federation of Kenya Employers	<p>Amend paragraph (1)(f) to read as follows—</p> <p>(f) one person nominated by the most representative employers body, the Federation of Kenya Employers and appointed by the Cabinet Secretary to represent the private sector.</p>	<p>To provide a clear criterion for nomination of the private sector representative to be appointed by the private sector.</p> <p>Health is an employment matter which falls under the Federation of Kenya Employers' mandate.</p>	
	Confraternity of Patients Kenya	<p>Amend subclause (1) to include one person representing patients as follows—</p>	<p>There is no person representing patients in the Board of the Agency.</p>	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		(ha) one person nominated by the Confraternity of Patients Kenya representing the interests of patients.		
	Association of Kenya Insurers	Amend subclause (1) to include one person to be nominated by the Association of Kenya Insurers.	Based on the volume of business, the interests of insurers in the medical field need to be protected.  The Association of Kenya Insurers represents 18 insurance companies that have a gross premium of 55 Billion Shillings, forming about a third of the insurance premium in Kenya.	
	Kenya Dental Association	Review paragraph (1)(g) to provide a clear criterion for appointment of the person and the private sector.	This is to ensure that the Board is constituted of competent persons.	
		Review paragraph (1)(h) to specify the nominating professional organizations, in this case—  (a) Kenya Medical Association (KMA); and  (b) Pharmaceutical Society of Kenya (PSK).	KMA and PSK are professional organizations that represent Pharmacists and Medical Officers and can be trusted to nominate competent health care providers to the board.	
	Health Records and Information	Amend paragraph (1)(g) to provide that the representative from counties include a nominee with knowledge	Health Records and Information Management actors are the main players in the data management	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
	Management Professionals	and skills in Health Records and Information Management.	cycle in all health facilities in Kenya.	
		Amend subclause (1) to provide that the chairperson for Health Records and Information Managers should be nominated to represent the professional interests of the members regulated by the board.	Health Records and Information Management professional ought to be represented. Health Records and Information Managers are regulated through Health Records and Information Managers Board.	
	Kenya Union of Clinical Officers	Amend to provide for nomination of two persons by the associations representing healthcare providers.	To include users and diversify the expertise.	
12	Christian Health Association of Kenya	Amend the clause to provide that— a) the Chief Executive Officer of the Agency serve for a term of three years, renewable once; and b) the Chief Executive Officer of the Agency be competitively recruited.	a) To ensure consistency with other legislation and therefore not serve for five years. b) To remove the option of secondment.	
	Health Records and Information Management Professionals	Amend paragraph (1)(b) to replace health information science with health information management.	Health Information Management Professionals is the known professional name.	
17	Insurance Regulatory Authority	*Amend the Bill to provide for procedures for access to health data by medical insurance providers.	To enable medical insurance providers properly assess their risk.	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
31	Confraternity of Patients Kenya	Amend subclause (1) to state—  (1) A healthcare provider shall ensure that he or she has obtained <u>informed</u> consent to process sensitive personal data.	This makes the patient have an informed choice on the action to undertaken.	
		Amend subclause (4) to state—  (4) A data subject who has issued a consent to the use or disclosure of personal data may withdraw their consent at any time by notifying the health care provider <u>orally or in writing</u> .	There are times a patient is unable to write and therefore ought to be given a choice of withdrawing consent orally as and when they want.	
35	Confraternity of Patients Kenya	Amend paragraph (1)(g) by deleting the word 'sensitive'.	Personal data is sensitive and therefore doesn't need qualification.	
36	Confraternity of Patients Kenya	Amend subclause (2) to state—  (2) A request under subsection (1) shall be made <u>orally or in writing</u> to the relevant health facility or health information bank.	The provision as is disadvantages patients who are unable to read and write and contravenes the right to personal data.	
42	Kenya Dental Association	Amend subclause (1) to include telepharmacy.	Telepharmacy is a critical component of e-Health.	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
43	Confraternity of Patients Kenya	Amend subclause (1) by inserting a new paragraph to state as follows— (i) ensure access to accountable and safe healthcare.	To arrest incidences of medical negligence.	
49	International Budget Partnership Kenya	Amend the Bill to provide clarity.	<p>The Clause 49 (b) states that; A healthcare provider shall ensure that the interaction in the e-health platform is undertaken in a manner that respects rights as prescribed by law. The bill defines e-health platforms as an ecosystem of hardware, software and technology used to deliver e-health services. What is the place of third-party platforms and how will clause 49(b) be actualized in the context of third-party platforms? An example is therapy sessions conducted on Zoom by psychologists.</p> <p>Will healthcare providers be required to develop their own e-health platforms? Will there be a standard approach considering integration with the health information system? What does this mean for existing platforms?</p> <p>Will there be a provision of digital literacy programmes or</p>	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
			overseeing digital literacy programs?	
52	International Budget Partnership Kenya	Amend the Bill to provide that reports be tabled in Parliament and be published and publicized in line with the PFM Act.	The bill does not place a requirement on the reports being Tabled in Parliament as well as being published and publicized in line with the PFM Act on an Agency funded by taxpayers.	
General	Ministry of Health	In support of the Bill.	The Bill was formulated in consultation with stakeholders and ought to be enacted as passed by the National Assembly.	
	Council of Governors	In full support of the Bill.	In support due to its potential to revolutionise health care delivery and improve patient outcomes through the integration of digital technologies.	
	International Budget Partnership Kenya	Amend the Bill to provide a clear definition of the roles of national and county governments in the delivery of e-health or digital services, taking inspiration from the E-Health Bill, 2023	The amendment is a vital step in ensuring the right level of government is budgeting and investing for the assigned function in the Constitutions and as may be defined in the Bill. The E-Health Bill, 2023 was tabled in the Senate on the 21st of July 2023. The bill bears striking similarity to the draft digital health bill tabled in the National	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
			<p>Assembly later on. While the Digital Health Bill is more comprehensive in its coverage of the different legislative considerations of the provision of digital health services, the E-Health Bill more explicitly provides more clarity on the role of national and county governments. This is crucial given the nascent nature of public digital health in Kenya and the specific roles given to national government (health policy) and county governments (health services).</p>	
		<p>Amend the Bill to—</p> <ul style="list-style-type: none"> <li>a) clarify its interlinkage with other existing laws;</li> <li>b) mitigate technology -based harm or unintended consequences for digital health technology; and</li> <li>c) provide for the training and enhancement of digital skills and knowledge of health workers medical and nursing professionals and set standards for provision of e-health services.</li> </ul>	<ul style="list-style-type: none"> <li>a) Generally, how does the proposed Digital Health bill interlink with other existing laws? This is to ensure that it's not viewed as a separate data collection but enhances data collection mechanisms that already exist. This is particularly important based on the role of the Kenya National Bureau of Statistics.</li> <li>b) There may be need for a provision for a secondary legislation that would mitigate technology -based harm or unintended consequences for</li> </ul>	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
			<p>digital health technology. Is there a plan to have such a provision in the bill?</p> <p>c) To ensure high quality provision of services, the Bill also needs to also provide for the training and enhancement of digital skills and knowledge of health workers medical and nursing professionals and set standards for provision of e-health services.</p>	
	Kenya Healthcare Federation	Review the Bill by taking cognisance and reviewing the Data Protection Act, the Health Act, the Environmental Management and Control Act and the National ICT Policy, 2019.	The Data Protection Act, the Health Act, the Environmental Management and Control Act and the National ICT Policy, 2019 need to be reviewed to adopt the aspirations of the bill which seems to borrow heavily and replicates aspects of already legislated upon matters which can be operationalized by publication of specific regulations on a case by case basis. The review and linkage of the other legal and policy framework will establish enabling environment for the seamless implementation of the existing laws and future regulations to be created.	

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		<p>Review the Bill to make provision for the following—</p> <ul style="list-style-type: none"> <li>a) elaboration of all forms of teleconsulting - telemedicine, telehealth, teledentistry, teleradiology and telecounselling;</li> <li>b) elaboration of forms of E-Health;</li> <li>c) elaboration of digital health components;</li> <li>d) setting up and operationalizing E-Health at section 103 and telehealth under the Health Act, 2017;</li> <li>e) setting up Health Data Protection regulations under the Data Protection Act, 2019 with a special directorate to oversight health data control and management;</li> <li>f) review and harmonize all aspects of existing regulations, draft and gazetted virtual health service providers, m-health, telehealth and e-health regulations;</li> <li>g) amend the Health Act, 2017 on the creation of DHA and CIHIS;</li> <li>h) consideration of harmonization of penalties under the Data Protection Act, 2019 and the Bill;</li> </ul>		

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		<ul style="list-style-type: none"> <li>i) consideration of establishment and actioning of internet connectivity standards requirements for each of the level of healthcare facilities;</li> <li>j) consideration that the Data protection commissioner is a technical person who is well-versed in their job and needs not to have their duties and mandates usurped in the guise that health data is too special to be handled by their office and needs to be housed under case of the CS Health which is a political office and appointment often times;</li> <li>k) harmonization of offences in Data Protection Act, 2019 and the penalties and offences proposed in the Bill;</li> <li>l) health data controllers and processors to be persons with healthcare background training as it makes it easier for data management and comprehension of system operations;</li> <li>m) alternatively, provide for various levels of access and system controls based on user's background training;</li> </ul>		

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		<p>n) maps of existing private healthcare systems HIS to be aligned to the CIDHIS;</p> <p>o) provide for qualifications of the chairperson of the Agency;</p> <p>p) ensure mechanism of business continuity in case of system breaches and crashes;</p> <p>q) provide within the law for continuous systems improvement and continuous training of all users of the health data systems;</p> <p>r) alignment with the Science, Technology and Innovation Act, 2013 and the Pharmacy and Poisons Board (Cap 244) when it comes to conducting healthcare research and dealing with sensitive health research data;</p> <p>s) some aspects of health data collected such as dental radiographs - orthopantomograms may require special ways to enforce data anonymization and minimization because of risk of personal data identification and abuse;</p> <p>t) align the meanings of consent as in Health Act, 2017 and Data</p>		

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		<p>Protection Act, 2019 with the consent descriptions of the Bill;</p> <ul style="list-style-type: none"> <li>u) in case IP rights in health data, provide elaborations in emerging health data ownership concepts;</li> <li>v) provide regulations and local listings and certifications of digital health products, software and pharmaceuticals made in Kenya;</li> <li>w) create regulations on how to maintain and manage all health systems users registers and access rights of CIDHIS in the whole country;</li> <li>x) create regulations on e-health/digital health e-learning/digital health literacy;</li> <li>y) create regulations on spread of healthcare misinformation and disinformation on social media and online spaces by unqualified and untrained persons and attachment of liability and provide recourse to any persons who rely on such forms of information;</li> <li>z) provide for statutory guide and regulations on health data monetization, meta-data mining and exploitation - AI and machine learning; and</li> </ul>		

CLAUSE	STAKEHOLDER	PROPOSAL	RATIONALE	COMMITTEE DETERMINATION
		aa) provide statutory guide and support on innovations in and around e-health and digital health.		