REPUBLIC OF KENYA

PARLIAMENT OF KENYA

THE SENATE

THIRTEENTH PARLIAMENT | SECOND SESSION

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 OKenyuri, MP
COMMITTEE	Health
CLERK AT THE TABLE	Abdirahman

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

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ABBREVIATIONS AND ACRONYMS

AKI	-	Association of Kenya Insurers
CHAK	-	Christian Health Association of Kenya
CoG	-	Council of Governors
COTU	-	Central Organisation of Trade Unions
FKE	-	Federation of Kenya Employers
IRA	-	Insurance Regulatory Authority
KHF	-	Kenya Healthcare Federation
MOH	-	Ministry of Health
NHIF	-	National Hospital Insurance Fund
RUPHA	-	Rural Private Hospitals Association
SHA	-	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. **Sen. Jackson Kiplagat Mandago, EGH, MP - Chairperson**
2. **Sen. Mariam Sheikh Omar, MP - Vice Chairperson**
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 11th 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, 14th September, 2023. The Bill was considered by the National Assembly and passed with amendments on Thursday, 27th 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, 3rd 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, 4th 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 –

	Name	Designation	Signature
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 11th 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, 14th September, 2023. The Bill was considered by the National Assembly and passed with amendments on Thursday, 27th 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, 19th 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, 4th 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 7th 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, 4th October, 2023. Receipt of memoranda on the Bill was closed on Saturday, 7th 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, 6th 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 Heathcare 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.**