

SPECIAL ISSUE

Kenya Gazette Supplement No. 117 (Senate Bills No. 32)



REPUBLIC OF KENYA

KENYA GAZETTE SUPPLEMENT

SENATE BILLS, 2023

NAIROBI, 21st July, 2023

CONTENT

Bill for Introduction into the Senate—	PAGE
The E-Health Bill, 2023	731

THE E-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—ROLE OF NATIONAL AND COUNTY GOVERNMENTS IN PROVISION OF E-HEALTH SERVICES

- 5.—Role of National Government in provision of e-Health Services.
- 6.—Role of county governments in the delivery of e-Health services.

PART III—ESTABLISHMENT OF TELEMEDICINE AND M-HEALTH SYSTEMS

- 7.—Principles.
- 8.—Establishment of the telemedicine and m-Health systems.
- 9.—Responsibilities of the Cabinet Secretary and the Council of County Governors.
- 10.—Establishment of e-Health centres.
- 11.—Components of a telemedicine and m-Health system.

PART IV—E-HEALTH PROVIDERS

- 12.—Persons who may deliver e-Health services.
- 13.—Registration of e-Health providers.
- 14.—Duties of health providers.
- 15.—Rights of patients in telemedicine and m-Health systems.

PART V—E-HEALTH INFORMATION

- 16.—Access to and sharing of information.
- 17.—Information rights for recipients of healthcare services.
- 18.—Healthcare identifiers.
- 19.—Establishment of registries.
- 20.—Interoperability and data exchange.
- 21.—Platform for the provision of store and forward services.
- 22.—Information to be set out in an e-Health database.
- 23.—Designation Order.
- 24.—Collection and use of health information.
- 25.—Application for disclosure of information for health research services.
- 26.—County health data stewardship committee.
- 27.—Functions of the Committee.

PART VI — E-WASTE

- 28.—Registration.
- 29.—Obligations of licence holders.
- 30.—Returns.
- 31.—Duration of licence.
- 32.—Cancellation of licence.
- 33.—Appeals.

PART VII — HEALTH TOURISM

- 34.—Accreditation.
- 35.—Obligations of an accreditation holder.
- 36.—Returns.
- 37.—Duration of the accreditation certificate.
- 38.—Cancellation of accreditation certificate.
- 39.—Appeals.

PART VIII — MISCELLANEOUS PROVISIONS

40.—Complaints.

41.—Public private partnership.

42.—Application of Act No. 24 of 2019.

43.—Regulations.

THE E-HEALTH ACT, 2023

A Bill for

AN ACT of Parliament to provide a framework for provision of Telemedicine; M-health; Health Tourism; licencing of health e-waste undertakings; the roles of the national and county governments; and for connected purposes

ENACTED by the Parliament of Kenya, as follows—

1. This Act may be cited as the E-Health Act, 2023.

Short title.

2. In this Act,—

Interpretation.

“Cabinet Secretary” means the Cabinet Secretary responsible for matters relating to health;

“county executive committee member” means the county executive committee member responsible for matters relating to health in the respective county;

“Data Commissioner” has the meaning assigned to it under clause 2 of the Data Protection Act;

No. 24 of 2019..

“electronic health records” means real-time, patient-centred records that make information available instantly and securely to authorized users;

“e-waste” has the meaning assigned to it under section 2 of the Sustainable Waste Management Act, 2022;

No. 31 of 2022.

“Healthcare identifier” means the national health identifier issued under section 17;

“e-Health” has the meaning assigned to it under section 2 of the Health Act;

No 21 of 2017.

“health information bank” means the collection of data organized and maintained in a platform that enables easy consultation and use by an e-health user;

“healthcare provider” has the meaning assigned to it under section 2 of the Health Act;

“information and communication technology” shall include—

- (a) compressed digital interactive video, audio or data transmission;
- (b) real-time synchronous view or web-conferencing communication;

- (c) secure web-based communication;
- (d) still image capture or asynchronous store and forward; and
- (e) modern smart medical device use for diagnosis and healthcare services;

“Ministry” means the Ministry of Health;

“m-Health” means the provision of health care services through the use of mobile devices;

“Authority” means the National Environmental Management Authority established under section 7 of the Environmental Management and Co-ordination Act;

“store-and-forward telemedicine services” means the process of storage, transmission and sharing of patient medical information by a healthcare provider in order to provide diagnostic and therapeutic assistance in the care of the patient without the patient or other healthcare provider being present in real time;

“telemedicine” has the meaning assigned to it under section 2 of the Health Act; and

“user” means healthcare providers, those seeking healthcare services and other stakeholders in the health sector.

3. The objects of this Act are to—

- (a) provide for the establishment, management and regulation of healthcare services delivered through the use of telecommunication devices;
- (b) facilitate the availability, timely access to and transmission of data and information necessary for the effective delivery of services by healthcare providers; and
- (c) provide measures to ensure interoperability, data interlinkage and security of medical records.

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

- (a) cost-effectiveness and efficiency for the delivery of e-health services;
- (b) integration with the existing health systems including the health information systems; and

- (c) protection of and preservation of the dignity of the patient in ensuring that patient information is private, confidential and secure and only used in the delivery of health services to such patient and is not put to inappropriate use.

PART II— ROLE OF NATIONAL AND COUNTY GOVERNMENT IN PROVISION OF E- HEALTH SERVICES

5. (1) The National Government shall, pursuant to section 103 of the Health Act —

Role of national government in provision of e-health services.

- (a) develop and implement national standards and ethics framework necessary for the delivery of e-Health services;
- (b) direct and co-ordinate the implementation of the e-health services and delivery of services at the National level of Government and for this purpose, integrate the e-health services into the existing health system at the National and county level of government;
- (c) ensure capacity building of human resources for health;
- (d) develop policy, standards and guidelines necessary to ensure that the data and information relating to patients is secure and protected;
- (e) develop policy, standards and guidelines necessary to facilitate the secure exchange of personal health information;
- (f) undertake continuous assessments of the telemedicine and m-Health systems to ensure effectiveness in its operation;
- (g) put in place measures to facilitate collaboration between the private and the public sector in ensuring the efficient and affordable delivery of telemedicine and m-Health services; and
- (h) collaborate with the relevant stakeholders; and
- (i) leverage on existing human, financial and technical resources in the implementation of telemedicine and m-Health system.

(2) The Cabinet Secretary shall in consultation with the Council of County Governors and the Cabinet Secretary responsible for Information and Communication Technology and for purposes of subsection (1) —

- (a) integrate e-Health services into the health systems established or existing at the national and county level of government;
- (b) develop the information and communication technology infrastructure necessary for the provision of the e-Health services;
- (c) collaborate with county governments in ensuring that the delivery of e-Health services at the county level are aligned with the national e-Health policy and standards;
- (d) designate national and regional centres and networks of excellence for the delivery of e-health best practices and policy co-ordination;
- (e) offer technical support to county governments in the delivery of e-Health services;
- (f) undertake research and implement programmes for the continuous advancement and effective implementation of the e-Health services;
- (g) collaborate with county governments and relevant stakeholders in the health sector in the conduct of capacity building and sensitization programmes regarding the implementation of the e-Health services;
- (h) formulate responsive plans and strategies for the implementation of e-Health services in collaboration with major stakeholders and affected sectors;
- (i) establish incentives to encourage and facilitate health facilities, healthcare providers, and other relevant stakeholders in investing in computing infrastructure for the delivery of e-Health services and adopt the use of e-Health solutions; and

- (j) monitor and evaluate the effectiveness of the e-Health services at the national and county levels of government.

6. Each county executive committee member shall, with respect to the e-Health services established in the respective county —

Role of county governments in the delivery of e-health services.

- (a) implement the guidelines and standards for the delivery of e-Health services put in place by Cabinet Secretary and the Cabinet Secretary responsible for Information, Communication and Technology;
- (b) collaborate with the National Government and relevant stakeholders in the health sector in the implementation of the e-Health services in the respective county;
- (c) monitor and evaluate the implementation, performance and effectiveness of the e-Health services in the respective county;
- (d) put in place the necessary infrastructure to ensure that the e-Health services are widely accessible by the residents of the county;
- (e) collaborate with the National Government in the building of capacity of human resources for health in the respective county in respect to e-Health services; and
- (f) carry out such sensitization programmes as may be necessary to create public awareness of the e-Health services.

PART III—ESTABLISHMENT OF TELEMEDICINE AND M-HEALTH SYSTEMS

7. The National Government and the county governments shall, in developing, implementing and maintaining a telemedicine and m-Health system, adhere to the following principles —

Principles.

- (a) user involvement and patient-centred delivery of services;
- (b) privacy, confidentiality and security of information;

- (c) preservation of the dignity of the patient in ensuring that patient information is only used in the delivery of health services to such patient and is not put to inappropriate use;
- (d) integration with the existing health systems including the health information system;
- (e) consent in the delivery of e-Health services; and
- (f) continuous research and development to ensure improvement of e-Health services.

8. (1) The National and county governments shall establish a telemedicine and m-Health system.

Establishment of the telemedicine and m-Health systems.

(2) The Cabinet Secretary and the Council of County Governors shall collaborate and co-operate with the Cabinet Secretary in charge of Information Communication and Technology in the development and establishment of an integrated telemedicine and m-Health system at the national and county level of government and shall, for this purpose —

- (a) formulate policies and standards for the implementation and regulation of the telemedicine and m-Health sector at the national and county level of government;
- (b) align the telemedicine and m-Health system with existing healthcare systems and ensure that the system provides a platform for the better delivery of health services;
- (c) develop policy, standards and guidelines necessary to ensure that the data and information relating to patients is secure and protected;
- (d) develop policy, standards and guidelines necessary to facilitate the secure exchange of personal health information;
- (e) undertake continuous assessments of the telemedicine and m-Health systems to ensure effectiveness in its operation;
- (f) put in place measures to facilitate collaboration between the private and the public sector in ensuring the efficient and affordable delivery of telemedicine and m-Health services; and

- (g) collaborate with the relevant stakeholders and leverage on existing human, financial and technical resources in the implementation of telemedicine and m-Health system.

9. In developing and establishing the telemedicine and m-Health system, the Cabinet Secretary and the Council of County Governors shall ensure that —

Responsibilities
of the Cabinet
Secretary and the
Council of County
Governors.

- (a) the system is accessible, user friendly and enables a person to make a free and informed choice regarding their health;
- (b) all citizens are able to securely access information relating to—
 - (i) their own health; and
 - (ii) medical facilities and the health services available;
- (c) an authorised person is able to securely access information relating to the patient;
- (d) the telemedicine and m-Health systems support healthcare services for persons living in remote areas, persons with special needs or persons who are unable to access a health facility upon the occurrence of an illness;
- (e) the system facilitates data porting of information relating to a patient to allow the patient and an authorised health care provider to access the health information of the patient when the patient is referred; and
- (f) a platform exists that enables a person to document and share information about his or her own health and which may serve as a resource for both the health provider and the person.

10. (1) Each national and county government shall, for the purposes of this Act and in accordance with the national policy —

Establishment of
e-health centres.

- (a) establish such e-Health centres as it considers necessary for the effective delivery of health services in the country;
- (b) equip the e-Health centres with the equipment and human resource necessary for the delivery of e-Health services; and

- (c) collaborate with the Ministry of Health in the conduct of continuous training programmes for health personnel within the county.

(2) In establishing an e-Health centre, the Cabinet Secretary and county executive committee member shall ensure that such centre is—

- (a) equipped with the necessary information and communication technology infrastructure to enable the centre deliver its services efficiently;
- (b) supervised and staffed by trained personnel;
- (c) inspected on a periodic basis; and
- (d) aligned to the national policy and meets the standards on the delivery of e-Health services prescribed by regulation.

(3) The county executive committee member, in consultation with the Cabinet Secretary, may designate a hospital under the management of the respective county as an e-Health centre.

11. In establishing and implementing the telemedicine and m-Health system under this Act, the Cabinet Secretary and the county executive committee members shall—

Components of a telemedicine and m-Health system.

- (a) engage with healthcare providers at the national and county levels of government and put in place mechanisms for the accessibility and co-ordinated delivery of healthcare;
- (b) put in place a system for securely sharing patient information and treatment options across geographical and health sector boundaries through the use of common standards on data structure, technologies and messaging;
- (c) develop standards for software certification or accreditation of e-Health solutions;
- (d) define the standards of delivery of e-Health services;
- (e) put in place a mechanism that supports and establishes information and communication technology as a tool to enable the exchange of information across the country by healthcare providers and the respective patients;

- (f) develop the workforce necessary to implement the telemedicine and m-Health system at the national and county level of government;
- (g) decentralise the delivery of e-Health services to the lowest unit of service delivery at the county level of government; and
- (h) put in place the necessary strategies and plans for the continuous development, operation and maintenance of the telemedicine and m-Health system.

PART IV — E-HEALTH PROVIDERS

12. No person other than—

Persons who may deliver e-Health services.

- (a) a healthcare provider holding a valid licence issued by the relevant regulatory body; or
- (b) an institution or firm holding a license issued by the relevant regulatory body may practice telemedicine or m-Health services.

13. (1) All telemedicine and m-Health health providers and health facilities shall be registered by the relevant regulatory bodies in the prescribed manner.

Registration of e-health providers.

(2) The Cabinet Secretary shall in consultation with the professional regulatory bodies prescribe regulations for the registration of telemedicine and m-Health health facilities and healthcare providers.

14. (1) All telemedicine and m-Health healthcare providers and health facilities shall ensure that they have obtained written consent from a patient before carrying out their duties under this Act.

Duties of healthcare providers.

(2) A telemedicine and m-Health healthcare provider engaged in the provision of telemedicine and m-Health services under this Act, shall—

- (a) obtain the legal consent of a patient before recording or capturing their information for the purposes of providing e-health services;
- (b) ensure confidentiality of patient information;
- (c) provide the highest standard of care to patients undergoing treatment;

- (d) adhere to the duties of a healthcare provider specified under section 8 of the Health Act;
- (e) provide prompt and accurate data necessary for treatment of patients;
- (f) ensure efficient and effective provision of telemedicine and m-Health services;
- (g) respect the patient's right to dignity, privacy and autonomy;
- (h) ensure that patients have access to their own data; and
- (i) inform a patient about the medical equipment, system, tool or application that shall be used in the provision of telemedicine and m-Health services to that patient.

(3) Where a patient is a minor or is incapacitated, the parent or appointed guardian 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 Health Act.

(4) Every healthcare provider under this Act shall—

- (a) collaborate and co-ordinate with other healthcare providers, health management organizations and health consumers in the provision of information, electronic consultations or other medical services; and
- (b) be entitled to access to an integrated or single view of their respective patients' health information at the point of care.

(4) Nothing in this Act shall prevent a patient from seeking compensation for injury arising from breach of duty by a healthcare provider in Court under this Act.

15. A patient who is undergoing treatment through the provision of telemedicine and m-Health shall have the right to —

Rights of patients
in telemedicine,
m-Health.

- (a) prompt and effective medical services;
- (b) obtain information concerning their data; and
- (c) object to the inclusion of references and sensitive data including individual medication data for a concrete treatment or care case.

PART V— E-HEALTH INFORMATION

16. (1) In establishing and implementing the telemedicine and m-Health system under this Act, the Cabinet Secretary and the county executive committee members shall, in consultation with the Cabinet Secretary responsible for Information and Communication Technology and the office of the data commissioner —

Access to and sharing of information.

- (a) ensure that health information on the telemedicine and m-Health platforms for patients and physicians is available in English, Kiswahili and, where necessary, the local language;
- (b) put in place the necessary infrastructure to enable online access to e-health services across the country;
- (c) put in place mechanisms that enable the delivery of e-Health services through various platforms including mobile devices, telemedicine centres and community digital centres to facilitate access to information;
- (d) facilitate the use of e-Health services by caregivers in geographically isolated communities to provide healthcare services; and
- (e) put in place the necessary infrastructure to promote the cross-border sharing of health information about the medical incidences and history of a particular patient by healthcare providers without compromising the right to privacy of the patient.

(2) The Cabinet Secretary shall, in consultation with the Cabinet Secretary responsible for information and communication technology, the Office of the Data Commissioner and the Council of County Governors shall for the purposes of subsection (1), prescribe—

- (a) standards regulating the capture, storage and sharing of information relating to patients;
- (b) regulations for the transmission of information in a manner that ensures confidentiality and that the integrity of data is maintained during transmission;

- (c) the manner in which information is shared between healthcare providers and between patients and their healthcare providers;
- (d) guidelines for the administration of the telemedicine and m-Health services; and
- (e) a framework for the efficient interoperability of the various telemedicine and m-Health systems and services.
- (f) conditions for access and use of patient information.

17. (1) Every person receiving healthcare services through the telemedicine and m-Health system shall have the right to—

Information rights for recipients of healthcare services.

- (a) access to quality and reliable health information;
- (b) access to a telemedicine and m-Health system that is private, secure and ensures confidentiality;
- (c) access to their electronic health records;
- (d) access and manage their personal health records; and
- (e) interact with their healthcare providers.

(3) The Cabinet Secretary shall, in collaboration with the county executive committee members and, for the purposes of subsection (1),—

- (a) integrate into the telemedicine and m-Health system, a health reporting system that is able to generate quality information and support effective decision making with respect to a patient;
- (b) undertake sensitization and capacity building programmes on the effective access, use and dissemination of information under the telemedicine and m-Health system; and
- (c) provide the necessary technical support to all users of the telemedicine and m-Health system and may for this purpose, establish such number of tele-call centres as may be necessary for the provision of adequate technical support.

18. (1) The Cabinet Secretary shall, in collaboration with the Council of County Governors, —

Healthcare
identifiers.

- (a) establish a national health identifier system for the effective delivery of patient centred healthcare services under this Act; and
- (b) assign to every healthcare recipient, individual healthcare provider and healthcare provider organisation, a national health identifier that is unique to that person or organisation.

(2) The Cabinet Secretary in consultation with, the Cabinet Secretary responsible for Information and Communication Technology, the Council of County Governors and the office of the Data Protection Commissioner shall prescribe the data sets to be captured in the national and county health identifier system.

(3) Without prejudice to the generality of the foregoing, the data sets prescribed shall include,—

- (a) in the case of an individual person, the —
 - (i) nationally assigned identification card number;
 - (ii) date of birth of the person;
 - (iii) name and gender of the person;
 - (iv) ethnicity of the person; or
- (b) in the case of an entity, the—
 - (i) registration number of the entity;
 - (ii) registered name of the entity; and
 - (iii) postal address and physical address; and
 - (iv) email address where available.

(4) The Cabinet Secretary shall prescribe standards and guidelines for the assignment of health identifiers at the national and county level of government.

19. (1) Each county executive committee member may establish a county health registry containing the health records with respect to all patients receiving treatment in a hospital falling within the mandate of the respective county government.

Establishment of
registries.

(2) The Cabinet Secretary shall, in consultation with the Records and Information Managers Board and Council of County Governors, prescribe standards for the establishment and management of registries established pursuant to this section.

No. 15 of 2016.

20. The Cabinet Secretary shall in consultation with the Cabinet Secretary responsible for Information and Communication Technology, the Council of County Governors and the office of the Data Protection Commissioner establish a framework for the interoperability of systems and devices necessary for implementing the telemedicine and m-Health system under this Act and shall, for this purpose—

Interoperability and data exchange.

- (a) prescribe standards and processes for the adoption of information and communication technology that facilitates interoperability between systems and devices in the telemedicine and m-Health system;
- (b) prescribe privacy and security standards and standards to address unique needs and situations;
- (c) regularly update and sensitize healthcare providers on the access and application of the system; and
- (d) put in place a mechanism for the effective and efficient transfer of information in a manner that retains the integrity of the information and ensures that the information is capable of interpretation in the manner that it was intended.

21. (1) Each county executive committee member shall for the effective implementation of the telemedicine and m-Health system in the respective county, establish an electronic system for the provision of store-and-forward services.

Platform for the provision of store-and-forward services.

(2) A patient receiving medical care by store-and-forward under subsection (1) above, shall be notified of the right to receive interactive communication with the distant specialist healthcare provider and shall receive an interactive communication with the distant specialist upon request.

22. (1) Each health care provider shall set up a confidential e-health database with respect to each health

Information to be set out in an e-health database.

care recipient under their care and to whom health care services are delivered under the telemedicine and m-Health system.

(2) A database established under subsection (1) shall include the following information with respect to each health care recipient —

- (a) the national health care identifier issued under section 18(1);
- (b) information required to verify the unique identifier issued to the health care recipient;
- (c) the name, date and place of birth;
- (d) physical address which shall include county of residence;
- (e) physical characteristics of the health care recipient;
- (f) any significant health or physical characteristics that require to be taken into account in administering any treatment to the health care recipient;
- (g) health data, including medical history of the family of the health care recipient;
- (h) information regarding the present and previous health care provider; and
- (i) such other information as the Cabinet Secretary or county executive committee may prescribe or which the health care provider may consider relevant.

(3) A healthcare provider shall not display or require information regarding the ethnicity of a patient.

(4) Treatment recommendations made through electronic means by a healthcare provider shall be held to the same standards of practice as those in traditional provider-patient setting.

23. (1) The Cabinet Secretary may, by order in the *Gazette*, establish or designate a database containing personal health information as a health information bank, if—

Designation order.

- (a) the database is in the custody or under the control of a health care provider; and
- (b) the collection and use of personal health information through the database is for a purpose set out in section 24 of this Act.

(2) The Cabinet Secretary shall, in issuing a designation order under subsection (1),—

- (a) identify the type or nature of personal health information to be contained in the health information bank, and the source of the personal health information;
- (b) in the case of a health information bank in the custody or under the control of a health care provider other than the Ministry responsible for health, authorize one individual who is an employee of the health care provider to administer the health information bank;
- (c) identify the purposes, for which personal health information may be collected and used through the health information bank;
- (d) identify the purposes, if any, for which personal health information may be disclosed from the health information bank;
- (e) authorize one or more persons to collect, use or disclose personal health information through the health information bank;
- (f) identify the persons from whom personal health information may be collected into the health information bank, including identifying whether personal health information may be collected other than directly from the individual whom the personal health information is about;
- (g) except in the case of disclosure for a health research purpose, identify to whom personal health information contained in the health information bank may be disclosed; and
- (h) identify the limits or conditions, if any, on the collection, storage, use or disclosure of personal

health information contained in or disclosed from a health information bank.

(3) A designation order may describe a person by name, title or position.

(4) A designation order is not effective until notice of the designation order is published in the Kenya Gazette and the respective county Gazette.

(5) If a health information bank is established or designated by a designation order, personal health information may be collected, used and, subject to section 24 of this Act.

24. (1) No person shall collect, use or divulge information relating to the health of a patient unless such information is necessary to—

Collection and use of health information.

- (a) identify an individual who is in need of or is receiving healthcare services and requires treatment;
- (b) provide health services to, or facilitate the care of the patient;
- (c) identify a person who is providing health services;
- (d) prevent or manage chronic conditions at the individual or population level;
- (e) facilitate health insurance and health service billing and in particular, with respect to—
 - (i) a payment in respect of health services or prescribed drugs, devices or pharmaceutical services to be made to or by the national government or a public body;
 - (ii) authorizing, administering, processing, verifying or cancelling such a payment;
 - (iii) resolving an issue regarding such a payment; or
 - (iv) audits by a county government or the Ministry responsible for health or the Office of the Auditor-General that makes reimbursement for the cost of health services or prescribed drugs, devices or pharmaceutical services;

- (f) assess and address public health needs;
- (g) engage in health system planning, management, evaluation or service delivery improvement including—
 - (i) health service development, management, delivery, monitoring and evaluation,
 - (ii) the compilation of statistical information,
 - (iii) public health surveillance, and
 - (iv) the assessment of the safety and effectiveness of health services;
- (h) conduct or facilitate research into health issues;
- (i) assess and address threats to public health; and
- (j) address such public health issue as the Cabinet Secretary may, by order, determine.

25.(1) A person who requires health information or data for the conduct of health research shall submit an application, in the prescribed form, to—

Application for disclosure of information for health research purposes.

- (a) in the case of information at the national level of government, the Cabinet Secretary; or
- (b) in the case of information at the county level of government, to the respective county executive committee member.

(2) A person shall, in making an application under subsection (1), submit to the Cabinet Secretary or the county executive committee member, as the case may be,

- (a) a verified official notification of the registered place of business in the case of a company or place of operation in the case of an individual applicant;
- (b) in the case of information required for purposes of conducting health research by a learning or research institution, a letter from the institution authorizing the applicant to conduct such research;
- (c) a statement on the purpose for which the information is sought;

- (d) the prescribed fee; and
- (e) such other information as the Cabinet Secretary or the county executive committee member may prescribe.

(3) The Cabinet Secretary or the county executive committee member, as the case may be, shall consider an application made under subsection (1) and may, if satisfied that the applicant meets the requirements of this Act and the requirements set out under subsection (4), issue a permit to the applicant upon payment of the prescribed fee.

(4) The Cabinet Secretary or the county executive committee member, as the case may be, shall not approve an application for the disclosure of health information under subsection (3) unless—

- (a) the request is for a health research purpose that cannot reasonably be accomplished unless the health information requested is disclosed;
- (b) the disclosure does not include information that would lead to the identification of individual persons;
- (c) if the protected information is contained in a health information bank, the disclosure is authorized under the terms of the applicable designation order;
- (d) the disclosure is on condition that it not be used for the purpose of contacting a person to participate in the health research, unless the county health director approves—
 - (i) the health research purpose;
 - (ii) the use of disclosed personal health information for the purpose of contacting a person to participate in the health research; and
 - (iii) the manner in which contact is to be made, including the information to be made available to persons contacted;
- (e) any data linkage is not harmful to the individuals who are the subjects of the health information, and

the benefits to be derived from the record linkage are clearly in the public interest; and

- (f) the Cabinet Secretary or the county executive committee member, as the case may be, has imposed conditions relating to—
 - (i) security and confidentiality of the information;
 - (ii) the removal or deletion of individual identifiers at the earliest reasonable time; and
 - (iii) the prohibition of any subsequent use or disclosure of personal health information without the express authorization of the Cabinet Secretary or the county executive committee member.

(5) The Cabinet Secretary or the county executive committee member, as the case may be, shall—

- (a) consider and determine the application within twenty-one days of receipt of the application; and
- (b) inform the applicant of the decision and issue to the applicant a permit in writing within seven days of such decision.

(6) The Cabinet Secretary or the county executive committee member, as the case may be, may, in issuing a permit under subsection (1), impose such conditions on the applicant as it considers necessary and may, from time to time, vary such conditions.

26. (1) The county executive committee member may, for the effective performance of the functions under section 25 and for the performance of any other function necessary for the effective implementation of this Act, establish a county health data stewardship committee.

County health data stewardship committee.

(2) Where a county executive committee member establishes a committee under subsection (1), it shall consist of —

- (a) the respective County Director of Health;
- (b) one person nominated by the respective county public service board; and
- (c) one person nominated by the Kenya Medical Practitioners and Dentists Council established

Cap. 253.

under section 3 of the Medical Practitioners and Dentists Act.

(d) one person nominated by the Health Records and Information Managers Board established under section 3 of the Health Records and Information Managers Act;

(e) one person nominated by the umbrella organisation representing faith-based health care service providers in that respective county;

No. 15 of 2016.

(3) The data stewardship committee shall be appointed by the respective county executive committee member by notice in the *Kenya Gazette* and county *gazette*.

(4) The persons nominated under subsection (1)(b), (c), (d) and (e) shall serve for a term of three years renewable for one further term.

(5) The data stewardship committee shall meet at least once every month and conduct its business and affairs in accordance with the schedule.

27. The county health data stewardship committee shall—

Functions of the Committee.

(a) consider applications for health data or information under section 25;

(b) monitor and evaluate the application and effectiveness of the health database;

(c) make recommendations to the county executive committee member on the management of health data;

(d) perform such functions as may be delegated to it by the respective county executive committee member or under any other written law.

PART VI—E-WASTE

28. (1) A person or entity shall not directly or indirectly handle e-waste unless the person is licensed by the Authority upon satisfaction of the prescribed conditions.

Registration.

(2) The Authority shall in consultation with the Ministry prescribe the requirements for licencing in subsection (1) above.

(3) An application for licencing under this section shall be in the form and manner prescribed the Cabinet Secretary in consultation with the Authority.

(4) A person who contravenes the provision of this section commits an offence and is liable, on conviction, to a fine not exceeding five million shillings or to imprisonment for a term not exceeding three years or both.

29. A licence holder shall adhere to prescribed conditions for the issuance of a licence. Obligations of licence holders.

30. A licence holder shall submit monthly returns to the Ministry of Health in the prescribed form. Returns.

31. (1) A licence issued by the licensing authority shall expire on 30th June of every year and a license holder wishing to renew the licence may apply by 1st June preceding the expiry of the licence. Duration of licence.

(2) Notwithstanding the provisions of sub-regulation (1), a late application may be made upon payment of a late application fee as may be prescribed.

32. The Authority may cancel a licence if the licensee Cancellation of licence.

(a) fails to meet any condition imposed by the Authority;

(b) fails to comply with the provisions of licensing; or

(c) surrenders the licence or permit to the relevant Authority together with a notice setting out a request that the licence be cancelled.

33. Where an applicant is dissatisfied with the decision of the Authority not to issue a licence under this Act, the applicant may make an application for judicial review to the High court within thirty days of the decision. Appeals.

PART VII—HEALTH TOURISM

34. (1) A health facility or health care provider shall not carry out the business of health tourism, unless the health facility or healthcare provider is accredited by the Medical Practitioners and Dentists Council upon satisfaction of prescribed conditions. Accreditation.
Cap 253.

(2) The Council shall in consultation with the Cabinet Secretary prescribe the requirements for accreditation in subsection (1) above.

(3) An application for accreditation under this section shall be in the form and manner prescribed by the Cabinet Secretary in consultation with the Council.

(4) A person who contravenes the provision of this section commits an offence and is liable, on conviction, to a fine not exceeding five million shillings or to imprisonment for a term not exceeding three years or both.

35. An accreditation holder shall adhere to prescribed conditions for the issuance of an accreditation certificate.

Obligations of an accreditation holder.

36. An accreditation holder shall submit monthly returns to the Ministry of Health in the prescribed form.

Returns.

37. (1) An accreditation certificate issued by the licensing authority shall expire on 30th June of every year and an accreditation holder wishing to renew the certificate may apply by 1st June preceding the expiry of the licence.

Duration of the accreditation certificate.

(2) Notwithstanding the provisions of subsection (1) above, a late application may be made upon payment of a late application fee as may be prescribed.

38. The Council may cancel an accreditation certificate if the accreditation holder—

Cancellation of accreditation certificate.

- (a) fails to meet any condition imposed by the Council in the accreditation certificate;
- (b) fails to comply with the provisions of this Act or regulations hereunder; or
- (c) surrenders the accreditation certificate to the Council together with a notice setting out a request that the accreditation certificate be cancelled.

39. Where an applicant is dissatisfied with the decision of the Council not to issue an accreditation certificate under this Act, the applicant may make an application for judicial review to the High court within thirty days of the decision.

Appeals.

PART VIII—MISCELLANEOUS PROVISIONS

40. (1) A patient who is aggrieved by an action or decision taken by a healthcare provider or any person under this Act may file a complaint under section 14 of the Health Act in the prescribed form.

Complaints.

No. 17 of 2017.

(2) A complaint filed under this Act shall be investigated in an expeditious manner in accordance with the procedures established under section 14(2) of the Health Act.

41. Subject to any other law regulating public-private partnerships, nothing under this Act shall prevent the national and county governments from entering into public-private partnerships for the purpose of establishing and deepening e-health service provision.

Public private partnership.

42. The Data Protection Act shall apply to the collection, processing and transmission of personal data by a health care provider or health facility under this Act.

Application of the Act No. 24 of 2019.

43. (1) The Cabinet Secretary, in consultation with the Council of County Governors, may prescribe regulations for the better carrying out of the provisions of this Act and without limiting the generality of the foregoing, the Cabinet Secretary may make regulations for—

Regulations.

- (a) the parameters to be considered for establishing a quality telemedicine and m-Health system;
- (b) the design and services that will be offered through the telemedicine and m-Health system;
- (c) the standards and guidelines to be adhered to in respect to data porting;
- (d) management of e-waste relating to health; and
- (e) health tourism.

SCHEDULE**s. 26 (5)****CONDUCT OF BUSINESS AND AFFAIRS OF THE
DATA STEWARDSHIP COMMITTEE**Meetings of the
Data Stewardship
Committee.

1. (1) The Data Stewardship Committee shall meet at least once in every three months to conduct the business of the committee.

(2) The Chairperson shall convene the ordinary meetings of the Data Stewardship Committee.

(3) Despite the provisions of subparagraph (1), the Chairperson shall, upon a written request by at least five members of the committee, convene a special meeting of the Data Stewardship Committee at any time where the chairperson considers it expedient for the transaction of the business of the committee.

(4) Unless three quarters of the total number of the members of the Data Stewardship Committee otherwise agree, at least fourteen days written notice of every meeting of the committee shall be given to every member of the committee by the Secretary.

(5) The quorum for the conduct of the business of the Data Stewardship Committee shall be five members.

(6) The chairperson shall preside at every meeting of the Data Stewardship Committee at which the Chairperson is present and in the Chairperson's absence, the members of the committee present shall elect one person from their number to preside over the meeting of the committee and that person shall have all the powers of the Chairperson.

(7) Unless a unanimous decision is reached, a decision on any matter before the Data Stewardship Committee shall be by a majority of the votes of the members present and voting and in the case of an equality of votes, the Chairperson or person presiding over the meeting shall have a casting vote.

(8) The proceedings of the Data Stewardship Committee shall not be invalidated by reason of a vacancy within its membership.

(9) Subject to provisions of this Schedule, the Data Stewardship Committee may determine its own procedure

and for the attendance of other persons at its meetings thereof.

2. (1) If a member of the Data Stewardship Committee is directly or indirectly interested in any matter before the committee and is present at a meeting of the committee at which the matter is the subject of consideration, that member shall, at the meeting and as soon as reasonably practicable after the commencement thereof, disclose the member's interest in the matter and shall not take part in the deliberations over, or vote on, the matter.

(2) A disclosure of interest made under this paragraph shall be recorded in the minutes of the meeting at which it is made.

MEMORANDUM OF OBJECTS AND REASONS

Statement of Objects and Reasons

The Bill seeks to enhance the delivery of medical services through the provision of e-Health services. As per the World Health Organisation, e-Health is the use of information and communication technologies (ICT) for health. E-Health will ensure equitable, affordable and convenient health services are delivered to all Kenyans.

The World Health Assembly in 2005 recognized the potential of e-Health to strengthen health systems and improve quality, safety and access to care, and encouraged Member States to take action to incorporate e-Health into health systems and services.

Section 104 of the Health Act, 2017 recognizes the importance of e-Health and states that within 3 years of the enactment of the Act, legislation shall be enacted to ensure the enhancement of e-health.

Part I of the Bill sets out the preliminary clauses used within the proposed legislation. In this part, various key definitions are comprehensively defined.

Part II of the Bill provides of the roles of National and county governments in provision of e-Health services.

Part III of the Bill provides for the establishment of telemedicine and m-Health system. It further provides for the principle to be adhered to when developing, implementing and maintaining a telemedicine and m-Health system. It also requires the establishment of e-Health centres and the components of a telemedicine or m-Health system.

Part IV of the Bill provides for the registration of health providers as telemedicine and m-Health providers.

Part V touches on e-health information. This part deals with various aspects of data in e-health systems as envisioned in the Bill. Data collection, exchange, protection and registries are also covered by the clauses in this part.

Part VI provides for licensing of persons or entities that wish to directly or indirectly wish to handle e-waste related to health by the National Environmental Management Authority.

Part VII provides for the accreditation of health facilities or health care providers to carry out the business of health tourism.

Part VIII contains the miscellaneous provisions of the Bill.

Statement on the delegation of legislative powers and limitation of fundamental rights and freedoms

The Bill once enacted, will compel the national and county governments to give effect to e-Health as encapsulated in the Health Act, 2017. The Bill does not limit fundamental rights and freedoms.

Statement on how the Bill concerns county governments

The proposed Bill concerns county governments in terms of Article 110(1)(a) as it concerns health which is a devolved function under paragraph 2 of Part 2 of the Fourth Schedule be compelling county governments to adhere to the provisions of section 104 of the Health Act, 2017.

Statement that the Bill is not a money Bill, within the meaning of Article 114 of the Constitution

The Bill is not a money Bill within the meaning of Article 114 of the Constitution.

Dated the 8th June, 2023.

HAMIDA KIBWANA,
Senator.

Statement on the delegation of legislative powers with limitation of fundamental rights and freedoms

The Bill does not conflict with the national and county governments to give effect to the Bill as provided in the Health Act. 2017. The Bill does not limit fundamental rights and freedoms.

Statement on how the Bill concerns county governments:

The proposed Bill concerns county governments in terms of Article 110(1)(a) as it concerns health which is a devolved function under paragraph 2 of Part 2 of the Fourth Schedule to the Health Act. 2017. The Bill does not limit fundamental rights and freedoms.

Statement that the Bill is not a money Bill, within the meaning of Article 114 of the Constitution

The Bill is not a money Bill within the meaning of Article 114 of the Constitution.

Dated the 8th day of 2017.

HAMISA KIBWANA,
Minister

