



LEGAL NOTICE NO.

THE DIGITAL HEALTH ACT
(No. 15 of 2023)

**THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS,
2024**

ARRANGEMENT OF REGULATIONS

Regulation

PART I- PRELIMINARY

- 1- Citation.
- 2- Interpretation.
- 3- Objects of the Regulations.

PART II – MANAGEMENT OF THE SYSTEM

- 4- Administration of the System.

PART III – THE ENTERPRISE SERVICE BUS

- 5- Enterprise service bus.
- 6- Onboarding onto the enterprise service bus.
- 7- Application for onboarding to the enterprise service bus.
- 8- Inventory of health data controllers.
- 9- Suspension from use of the enterprise service bus.
- 10- Maintenance of health data banks.

PART IV – SHARED OR COMMON RESOURCES

- 11- Shared resources.
- 12- The national health data dictionary.
- 13- The client registry.
- 14- The facility registry.
- 15- The telemedicine health provider registry.

- 16- The health worker registry.
- 17- The Kenya Health Enterprise Architecture.
- 18- Product catalogue.
- 19- The National Logistics Management Information Services Platform.
- 20- Shared health record.
- 21- Health Management Information Services Platform.
- 22- Insurance and finance services in the System.

SCHEDULES

THE DIGITAL HEALTH ACT
(No. 15 of 2023)

IN EXERCISE of the powers conferred by section 60(d) of the Digital Health Act, 2023, the Cabinet Secretary for Health, in consultation with the Board of the Digital Health Agency and the County Governments, makes the following Regulations—

THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS, 2024

PART I —PRELIMINARY

Citation. 1. These Regulations may be cited as the Digital Health (Data Exchange) Regulations, 2024.

Interpretation. 2. In these Regulations, unless the context otherwise requires—

No. 15 of 2023. “Act” means the Digital Health Act, 2023;

 “Agency” has the meaning assigned to it under section 2 of the Act;

 “aggregate data” means health data or information consolidated and stored in a single, central system for ease of access including service statistics or clinical data;

 “authorized access” means the legitimate and sanctioned entry, retrieval and processing of data within a system by an individual or an entity that has been granted explicit permission and privileges by a health data controller based on the roles and responsibilities of that individual or entity and the applicable policies governing the system of the health data controller;

 “Board” has the meaning assigned to it under section 2 of the Act;

 “Cabinet Secretary” has the meaning assigned to it under section 2 of the Act;

 “client” has the meaning assigned to it under section 2 of the Act;

 “County Executive Committee Member” has the meaning assigned to it under section 2 of the Act;

 “data controller” has the meaning assigned to it under section 2 of the Act;

 “data processor” has the meaning assigned to it under

section 2 of the Act;

“digital health solution” means a digital health application, intervention or initiative and includes digital health technology infrastructure including telehealth systems and electronic health information systems and the provision of education and training support for e-Health initiatives;

“health data” has the meaning assigned to it under section 2 of the Act;

“health data controller” has the meaning assigned to it under section 2 of the Act;

“health data processor” has the meaning assigned to it under section 2 of the Act;

“health worker registry” means the registry established and maintained in accordance with regulation 17;

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

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

“Office of the Data Protection Commissioner” means the office of the Data Protection Commissioner established under section 5 of the Data Protection Act;

Cap. 411C.

“System” has the meaning assigned to it under section 2 of the Act;

“telemedicine health provider” means a healthcare worker who is qualified, registered and licensed to practice in Kenya and who provides telemedicine services; and

“telemedicine platform” means the technology infrastructure, services, and support that enables the provision of healthcare services and sharing of medical knowledge over distance using telecommunications.

Objects of these Regulations.

3. The object of these Regulations is to provide for–

- (a) administration and management of the System;
- (b) exchange of health information within the System;
- (c) the establishment and implementation of the data exchange component of the System.

PART II —MANAGEMENT OF THE SYSTEM

Administration of
the System.

4. (1) In the administration of the System, the Agency shall be guided by—

- (a) the digital health standards issued by the Cabinet Secretary from time to time; and
- (b) in the case of the infrastructure, Information and Communication Technology Standards issued by the Cabinet Secretary for the time being responsible for matters relating to information and communication technology and digital economy.

(2) The Agency shall submit reports on the administration and management of the System and health data arising from the System to the Cabinet Secretary on a quarterly basis or as may be required by the Cabinet Secretary.

(3) The Agency may grant access to the System to a person from the Ministry responsible for matters relating to health or the respective county department responsible for matters relating to health for the purposes of analysis of data for—

- (a) reporting in compliance with subnational, national, regional and global reporting requirements;
- (b) decision making; and
- (c) policy formulation.

(4) A person to be granted under sub regulation (3) shall be designated by the Cabinet Secretary or the County Executive Committee Member.

(5) The level of access granted under this regulation shall be determined by the type of data required and the classification of health data specified in section 19 of the Act.

(6) Within six months of coming into force of these Regulations, a health data controller who was using or managing health data using a digital health solution shall be onboarded into the System.

PART III — THE ENTERPRISE SERVICE BUS

Enterprise service
bus.

5. (1) Pursuant to section 16(a) of the Act, the Information and Communication Technology environment of the system shall include an Enterprise Service Bus which shall—

- (a) route messages between certified digital health solutions;
- (b) monitor and control the routing of exchange of messages between certified digital health solutions;
- (c) resolve conflicts between communicating service components;
- (d) control the onboarding and versioning of certified digital health solutions;
- (e) monitor and eliminate redundant services; and
- (f) provide common services including—
 - (i) event handling;
 - (ii) data transformation and mapping;
 - (iii) message and event queuing and sequencing;
 - (iv) security or exception handling;
 - (v) protocol conversion.

(2) The Enterprise Service Bus shall include the following components—

- (a) National Health Information Exchange, which shall provide a platform for the standardization and secure sharing of health data;
- (b) Telemedicine platform, which shall provide infrastructure to support remote diagnosis, consultation, and treatment; and
- (c) National Logistics and Supply Chain Management Service, which shall coordinate the procurement, distribution, and inventory management of health commodities.

(2) The enterprise service bus shall be maintained in accordance with the interoperability standards developed under the Act.

Onboarding onto the enterprise service bus.

6. (1) A health data controller shall be onboarded as a user in the enterprise service bus.

(2) The Agency shall use a portal for purposes of onboarding health data controllers to the enterprise service bus.

Application for onboarding to the enterprise service bus.

7. (1) An application for onboarding as a user of the enterprise service bus shall be made to the Agency in Form 1 set out in the First Schedule and shall be accompanied by requirements based on the type and nature of the organization seeking to be onboarded including—

- (a) the particulars of a health data controller of a digital health solution including proof of registration with the Office of the Data Protection Commissioner;
- (b) a data protection impact assessment report for the digital health solution;
- (c) the particulars of the organization of the health data controller;
- (d) the particulars of the developer of the digital health solution;
- (e) the particulars of the digital health solution being onboarded;
- (f) a valid certificate of compliance issued upon the certification of the digital health solution; and
- (g) proof of payment of the onboarding fee set out in the Second Schedule.

(2) Upon receipt of an application under subregulation (1), the Agency shall review the application and notify the applicant of the outcome of the application within fourteen days from the date of the application

(3) Where an application under subregulation (1) is approved, the Agency shall give the user access to the enterprise service bus to a health data controller of a certified digital health solution by providing the health data controller with—

- (a) an internet address and ports;
- (b) an application programming interface endpoints;
- (c) authentication and authorization protocols; and
- (d) enterprise user licence.

(4) The enterprise user licence issued under this regulation shall be valid for a period of one year from the date of issue.

(5) An applicant who dissatisfied by a decision of the

Agency in relation to onboarding to the enterprise service bus may apply to the Complaints Committee for a review of the decision in accordance with the Digital Health (Health Information Management) Regulations, 2024.

Inventory of health data controllers.

8. (1) The Agency shall maintain an inventory of health data controllers of the certified digital health solutions onboarded onto the enterprise service bus in accordance with regulation 7.

(2) The inventory shall contain information including—

- (a) the particulars of the health data controller;
- (b) the particulars of the organization including on service delivery or healthcare management;
- (c) the particulars of the digital health solution; and
- (d) the enterprise user licence of the health data controller.

Suspension from use of the enterprise service bus.

9. (1) The Agency shall suspend a health data controller from the enterprise service bus where the—

- (a) digital health solution of the health data controller has a serious data breach that has not been resolved;
- (b) health data controller is not using the access rights for the intended purpose;
- (c) health data controller has facilitated unauthorized access to the enterprise service bus by a third party;
- (d) digital health solution of the health data controller is not valid;
- (e) health data controller fails to maintain the enterprise user licence;
- (f) health data controller fails to pay the applicable agency fees; and
- (g) health data controller infringes health regulations as reported by the relevant regulatory bodies.

(2) Where the health data controller is suspended under subregulation (1), the health data controller shall be blocked

from accessing the enterprise service bus.

(3) The Agency shall notify the health data controller of the blocked access to the enterprise service bus within three days from the date of the blocked access.

(4) A health data controller who is permanently blocked from accessing the enterprise service bus under subregulation (2) shall migrate health data in the enterprise service bus in accordance with the data migration guidelines issued under the Act.

(5) Where a health data controller resolves all compliance issues under subregulation (1), the data controller shall apply to the Agency for re-onboarding to the enterprise service bus.

(6) A health data controller re-onboarded to the enterprise service bus under subregulation (5) shall upload health data in the enterprise service bus in the manner set out in these Regulations.

Maintenance of
health data banks.

10. (1) The national health data bank and county health data bank shall comprise of centralized information systems that shall collate minimum data set client level and aggregate data processed by certified digital health solutions:

Provided that the certified digital health solutions shall be utilized in the respective county in the case of the county health data bank.

(2) Any health data transmitted to the national health data bank or the county health data bank shall be stored, reviewed, audited, updated and secured in accordance with the Act and the relevant laws including —

- (a) the security and cybersecurity standards and policies issued by the issued by the Cabinet Secretary for the time being responsible for matters relating to information and communication technology and digital economy; and
- (b) the prevailing information security standards issued by the Board of the Information and Communication Technology Authority.

(3) The Cabinet Secretary, through the Agency, or the County Executive Committee Member, as the case may be, shall make provision for—

- (a) the submission of the requisite data by certified digital health solutions to the national health data bank and

the county health data bank through the enterprise service bus;

- (b) access to data in the national health data bank and the county health data bank to the authorized institutions including to the relevant national systems in accordance with the Kenya Health Data Governance Framework.

(4) A County Executive Committee Member shall notify the Cabinet Secretary and the Agency of the intent to re-designate a county health data bank and such re-designation shall be guided by the guidelines issued by the Cabinet Secretary and the data centre standards issued by the Cabinet Secretary for the time being responsible for matters relating to information and communication technology.

PART IV—SHARED OR COMMON RESOURCES

Shared resources.

11. (1) Pursuant to section 16(e) of the Act, the System shall consist of the shared or common resources which shall be maintained in accordance with this Part.

(2) The users and consumers of the shared resources in the System shall pay a service fee for use of the System.

The national health data dictionary.

12. (1) The national health data dictionary in the System shall be the single source of reference of health terminology in Kenya.

(2) All users of the System shall use the national health data dictionary as the data reference dictionary.

(3) In the administration of the System, the Agency shall be responsible for the day-to-day management and maintenance of the national health data dictionary and in particular shall—

- (a) ensure that the national health data dictionary is available, updated and comprehensive;
- (b) enable a certified digital health solution to access and utilise the national health data dictionary;
- (c) regularly inform stakeholder in the digital health sector on key components of the national health data dictionary affecting health data terminology;
- (d) update the national health data dictionary guided by factors including—

- (i) emerging concepts or domains;

- (ii) the adoption of new standards;
- (iii) the existence of obsolete concepts or domains;
- (iv) data quality assessments;
- (v) the changes in security protocols; and
- (vi) continuous improvement concepts.

The client registry.

13. (1) The client registry in the System shall be the single source of reference in the identification of clients seeking health services.

(2) In the administration of the System, the Agency shall be responsible for the day-to-day management and maintenance of the client registry and in particular shall—

- (a) enable certified digital health solutions to access and utilise the client registry; and
- (b) provide for self-registration of in the client registry through the patient portal using Form 2 set out in the First Schedule.

(3) A client or patient shall be registered in the client registry through a certified digital health solution.

(4) During the registration of a client or patient to the client registry —

(a) a Kenyan citizen shall provide—

- (i) a national identity card;
- (ii) a valid passport; or
- (iii) a birth certificate in the case of a person under the age of eighteen years;

(b) a person who is not a Kenyan citizen and is ordinarily resident in Kenya shall provide a valid—

- (i) asylum-seeker pass;
- (ii) movement pass;
- (iii) letter of recognition;

(iv) refugee identification card;

(v) conventional travel document.

(5) A health insurance provider shall—

(a) ensure that all its clients are registered in the client registry; and

(b) cause a client to be registered in the client registry where the health insurance provider is enrolling a client who is not registered in the client registry.

(6) A certified digital health solution shall, upon to the payment of the applicable fee by the responsible digital healthcare provider, be granted access to the client registry to identify clients and patients and to verify their identity information.

The facility
registry.

14. (1) The facility registry in the System shall be the single source of reference for health facilities in Kenya.

(2) The facility registry shall contain information on—

(a) the particulars of the health facility including the contact information;

(b) the geo-location details of the health facility;

(c) the contact details of the health facility;

(d) the regulatory details of the health facility;

(e) the list of services offered by the health facility;

(f) the infrastructure details of the health facility; and

(g) the human resources responsible for health in the health facility

(3) A healthcare provider, owner of a health facility or the County Director of health shall upload the information specified by the Cabinet Secretary into the facility registry including—

(a) a licence issued by the relevant regulatory body;

(b) a certificate of registration of the health facility by the relevant regulatory body;

(c) the inspection report of the health facility; and

(d) the duly completed checklist of the health facility.

(4) In the administration of the System, the Agency shall be responsible for the day-to-day management and maintenance of the facility registry and in particular shall—

(a) assign a Kenya Master Facility List Code to a health facility; and

(b) designate a portal in the facility registry where healthcare providers or health facilities may regularly update their information including on the services offered and the infrastructure owned.

(5) A healthcare provider or owner of a health facility shall be responsible for the accuracy of the information uploaded on the facility registry.

(6) A healthcare provider or owner of a health facility who submits false or misleading information to the Portal and the Facility Registry commits an offence and shall, on conviction, be liable to the penalty specified under section 59(1) of the Act.

The telemedicine
health provider
registry.

15. (1) The telemedicine health provider registry in the System shall be the single source of reference in the provision of telemedicine in Kenya.

(2) The telemedicine health provider registry shall contain a list of all e-health service providers including telemedicine health providers.

(3) The telemedicine health provider registry shall contain information on—

(a) the certified digital health solution being utilised by the telemedicine health provider;

(b) the particulars of the health data controller;

(c) the regulatory details of the telemedicine health provider;

(d) the list of services offered by the telemedicine health provider; and

(e) proof of registration as a health data controller or health data processor by the Office of the Data Protection Commissioner.

(4) The Agency shall issue a telemedicine provider code for a telemedicine health provider that meets the requirements

provided under this regulation.

(5) A telemedicine health provider shall—

- (a) use a digital health solution certified in accordance with the Act for service delivery; and
- (b) prepare a report of the health data arising from the provision of e-health services in the manner specified in the Act.

(6) In the administration of the System, the Agency shall be responsible for the day-to-day management and maintenance of the telemedicine health provider registry and shall certify all e-health and telemedicine platforms in accordance with the Certification Framework set out in the Digital Health (Use of e-Health Applications and Technologies) Regulations, 2024.

The health worker registry.

16. (1) The health worker registry in the System shall be the single source of reference for all information related to health workers for purposes of health information exchange and accessing the System.

(2) The health worker registry shall contain information on—

- (a) the personal details of a health worker;
- (b) the qualifications of a health worker;
- (c) the details of the relevant regulatory body that licensed or registered the health worker as provided by the regulatory body or the health data controller; and
- (d) where applicable, a valid practice licence details of the health worker.

(3) In the administration of the System, the Agency shall maintain an up-to-date health worker registry integrated with the various information systems owned and maintained by the regulatory bodies.

(4) A health worker shall, subject to proof of valid licensing by the relevant regulatory body, apply to the Agency for registration to access the health worker registry

(5) An application for registration under subregulation (4) shall be made through the portal in Form 3 set out in the First Schedule.

(6) Upon receipt of an application under subregulation (4), the Agency shall validate the information submitted and where the health worker is qualified—

- (a) register the health worker in the health worker registry; and
- (b) issue a unique identifier to the health worker for purposes of accessing and using the System.

(6) The Agency may reject an application under subregulation (4) where the health worker—

- (a) does not have a valid practicing licence issued by the relevant regulatory body;
- (b) is deregistered by the relevant regulatory body;
- (c) has contravened the provisions of the Act or these Regulations;
- (d) has been dormant for a period exceeding five years.

The Kenya Health Enterprise Architecture.

17. In the administration of the System, the Kenya Health Enterprise Architecture shall be the reference point for the Agency in the performance of its functions under the Act.

(2) The Agency shall ensure that the digital health ecosystem including the certification processes adheres to the Kenya Health Enterprise Architecture.

(3) The Kenya Health Enterprise Architecture shall be reviewed every three years or as need arises as may be determined by the Cabinet Secretary.

(4) The review under subregulation (3) shall be conducted in consultation with the relevant stakeholders and shall be guided by the considerations recommended by the Cabinet Secretary or the Board including —

- (a) the Kenya Health Sector Strategic Plan;
- (b) the significant technological advances;
- (c) the changes in system scalability; and
- (d) prevailing industry practices.

Product catalogue.

18. The product catalogue in the System shall be the comprehensive register of all registered health products and technologies in the country including digitally enabled medical

equipment.

(2) The product catalogue shall contain information on health product or technology including—

- (a) the identification of the health product or technology by the unique product identifier in accordance with the prevailing policy;
- (b) the generic name or international non-proprietary name of the health product or technology;
- (c) the strength of the health product or technology;
- (d) the formulation of the health product or technology;
- (e) the route of administration of the health product or technology;
- (f) the class of the health product or technology;
- (g) the brand name of the health product or technology; and
- (h) the status of the health product or technology.

(3) The health products and technologies in the product catalogue shall have a standardized unique health product and technology identifier issued by the Pharmacy and Poisons Board through the System.

(4) The Agency shall, in collaboration with the Pharmacy and Poisons Board, ensure that the product catalogue is up to date.

The National
Logistics
Management
Information
Services Platform.

19. (1) The National Logistics Management Information Services Platform in the System shall be the main reference point in the reporting, tracking and tracing of quantities, statuses and location of all health products and technologies.

(2) The National Logistics Management Information Services Platform shall contain information on a health product or technology including—

- (a) the identification of a health product or technology as set out in the product catalogue provided under regulation 18;
- (b) the batch details of a health product or technology;
- (c) the quantities of a health product or technology;

(d) the manufacturing information of a health product or technology including the—

(i) name of the manufacturer;

(ii) manufacture date; and

(iii) date of expiry of the health product or technology;

(e) the location of a health product or technology; and

(f) the status of a health product or technology including—

(i) the condition of a health product or technology; and

(ii) the usage of the health product or technology.

(3) In the administration of the System, the Agency shall be responsible for the day-to-day management and maintenance of the National Logistics Management Information Services Platform and in particular shall—

(a) administer the National Logistics Management Information Services Platform guided by the National Logistics Management Information Services standards;

(b) ensure that the National Logistics Management Information Services Platform provides information on health products and technologies to ensure health products and technologies conform to the standards of quality, safety and efficacy set by the Pharmacy and Poisons Board pursuant to section 3B (2)(b) and (d) of the Pharmacy and Poisons Act;

(c) ensure that a person using or managing a logistics management information system to authenticate, track or trace a health product or technology conforms to the National Logistics Management Information Services standards;

(d) ensure that the National Logistics Management Information Services Platform provides commodity visibility and operational management of the national supply chain;

(e) grant access to the National Logistics Management

Information Services Platform to a certified digital health solution being used by a health facility or a supplier of a health product or technology for purposes of tracking and tracing of health products and technologies.

(3) A supplier of a health product or technology shall apply for registration into the National Logistics Management Information Services Platform.

(4) An application for registration into the platform under subregulation (3) shall be made to the Agency in Form 4 set out in the First Schedule and shall be accompanied by the onboarding into the platform fee set out in the Second Schedule.

(5) Where an application under subregulation (4) is approved, the Agency shall register the suppliers in the National Logistics Management Information Services Platform.

(6) A supplier or provider of a health product or technology shall electronically report on the information set out in subregulation (2) through—

- (a) the National Logistics Management Information Services Platform; or
- (b) an appropriate system that is interoperable with the National Logistics Management Information Services Platform.

(7) A supplier or provider of a health product or technology shall pay the annual retention in the platform fee set out in the Second Schedule.

Shared health
record.

20. (1) The shared health record in the System shall be the single source of reference for the medical history of patients in the System

(2) In the administration of the System, the Agency shall be responsible for the day-to-day management of the shared health record and in particular shall—

- (a) maintain the Shared Health Record in the defined standard format containing the minimum data set for purposes of ensuring patient data portability, continuity of care, billing and settlement of claims;
- (b) maintain a longitudinal record of every encounter from an application of a digital health solution in the format set by the Cabinet Secretary;

- (c) grant a client access to their personal Shared Health Record through the patient portal designated by the Agency; and
- (d) audit the log of access shared by a certified digital health solution for purposes of enhancing compliance and evaluating trends in authorized and unauthorized access.

(3) A digital health solution certified by the Agency shall, in relation to the shared health record, —

- (a) query and update the shared health record for every encounter with a client;
- (b) provide an electronic alert to a client where access to the shared health record is identified; and
- (c) maintain an auditable log of all access that has taken place in the Shared Health Record indicating the users, data entry, retrieval, manipulation and frequency of the access.

(4) Every client encounter in the shared health record shall be updated within twenty-four hours of the client encounter.

(5) A health data controller handling health data shall be responsible for updating the shared health record and shall—

- (a) transmit or share encrypted health data within twenty-four hours of the collection of the data in the prescribed format;
- (b) ensure that the transmitted health data contains the minimum data set issued by the Agency in the format set by the Cabinet Secretary;
- (c) retain a copy of the health data transmitted as specified in section 25(1) of the Act; and
- (d) keep a metadata log of the transmissions made under this regulation.

(6) Despite subregulation (4) and (5), a health data controller may transmit health data within a period not exceeding seven days in exceptional circumstances including where—

- (a) the digital health solution is offline; or
- (b) a special situation beyond the control of the health

data controller occurs as may be approved by the Agency.

(7) A health data controller who fails to—

- (a) transmit health data to the Shared Health Record commits an offence and shall, on conviction, be liable to the penalty specified under section 59(2) of the Act;
- (b) comply with the provisions on the transmission of sensitive personal data as provided in the Act and these Regulations commits an offence and shall, on conviction, be liable to the penalty specified under section 59(1) of the Act.

(8) The access of the shared health record of a client by a health data controller shall be limited to the particular encounter of the health data controller and the client.

(9) A client may, besides the data in the Shared Health Record, request further information from the health data controller in writing, and where such request is made, the respective health data controller shall provide the requested information within a period of seventy-two hours from the date of the request.

(10) A health data controller may, subject to consent by the client to whom the information relates, request for information held by another health data controller in a certified digital health solution for purposes of the provision of healthcare services.

Health
Management
Information
Services Platform.

21. (1) The Agency shall maintain the Health Management Information Services Platform in the System for reporting purposes.

(2) The Health Management Information Services Platform shall contain a public portal for the sharing information on—

- (a) matters of public interest;
- (b) summary statistics, dashboards and information on key metrics relevant on diseases and events of public health in Kenya; and
- (c) select aggregate health data published in various formats for easy consumption by various stakeholders including the members of public.

(3) A certified digital health solution shall report on the

minimum data set in the format specified by the Agency.

(4) A health data controller handling health data shall ensure that all providers under the jurisdiction of the health data controller comply with the specified reporting obligations for the Health Management Information Services Platform.

(5) A health data controller who fails to submit reports to the Health Management Information Services Platform commits an offence and shall, on conviction, be liable to the penalty specified under section 59(2) of the Act.

(6) The aggregate health data for publication under subregulation (5) shall be based on various criteria including—

- (a) the disease burden;
- (b) the public health events;
- (c) the diseases; or
- (d) the health-related events of public interest

(7) In the management of the Health Management Information Services of the System, the Agency shall —

- (a) provide access for reporting purposes under the Health Management Information Services Platform to the relevant institutions in accordance with the Kenya Health Data Governance Framework including access by health data controllers and health data processors to data generated and reported by them in the Health Management Information Services Platform;
- (b) review and update the information in the public portal in the Health Management Information Services Platform;
- (c) during the certification process, ensure that the certified digital health solution has capacity to comply with the reporting obligations for the Health Management Information Services Platform; and
- (d) provide the minimum data set for reporting as determined by the Cabinet Secretary including—
 - (i) immediate diseases as they occur;
 - (ii) electronic integrated disease surveillance and response;

- (iii) public health events as they occur;
- (iv) disease or events of international concern;
- (v) disease registries; and
- (vi) routine reporting.

Insurance and
finance services
in the System.

22. (1) For purposes of insurance and finance services in the System, a digital health solution certified by the Agency shall provide comprehensive costing of the healthcare services provided to clients.

(2) The claims management system of a health insurance provider shall, for purposes of identifying clients accessing healthcare services, reference the client registry.

(3) In the administration of health insurance services in the System, the Agency shall—

- (a) assess and certify the claims management systems of health insurance providers;
- (b) provide access to the certified claims management systems of health insurance providers to an invoiced clinical encounter contained in the shared health record;
- (c) ensure that claims to the Social Health Authority adhere to the tariffs set out in the Tariffs Registry developed by the Agency in collaboration with the Board of the Social Health Authority;
- (d) charge the service fees set out in the Second Schedule for a claim or any financial settlement raised by a health insurance provider through the shared health record.

(4) The Tariffs Registry referred to under subregulation (3)(c) shall contain information as may be determined by the Agency including the—

- (a) healthcare benefits package as gazetted by the Cabinet Secretary in consultation with the Board of the Social Health Authority; and
- (b) actual cost of the healthcare services provided to a client.

FIRST SCHEDULE

FORM 1 ((r. 7(1)))

**REPUBLIC OF KENYA
DIGITAL HEALTH ACT, NO. 15 OF 2023
THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS,
2024**

APPLICATION FOR ONBOARDING TO THE ENTERPRISE SERVICE BUS	
Details of the Health Data Controller	
•	TITLE:
•	FULL NAME:
•	SEX
•	ID/PASSPORT NO.:
•	ORGANIZATION NAME:
•	POSITION IN THE ORGANIZATION:
•	EMAIL ADDRESS:
•	COUNTY:
•	TEL NO.:
•	PROOF OF REGISTRATION WITH THE ODPC
(Reg. no.):	
DETAILS OF THE DATA PROTECTION OFFICER	
•	NAME:
•	SEX
•	ID/PASSPORT NO.:
•	POSITION IN THE ORGANIZATION:
•	EMAIL ADDRESS:
•	TEL NO.:
ORGANIZATIONAL DETAILS	
•	TYPE OF ORGANIZATION
☐ Health Facility	Health Insurance Company
☐ County	Other ☐
•	If Other Please Specify:
HEALTH FACILITY ONBOARDING	

• ATTACH SCHEDULE OF THE FACILITY/FACILITIES TO BE ONBOARDED (MFL code, Name of facility, Facility In-charge, Digital Health solution(s) name and version):	
APPLICATION DETAILS	
• TYPE OF APPLICATION (Tick appropriately)	
☐ New Application	Re-onboarding ☐
• SHARED RESOURCES TO BE ACCESSED (TICK APPROPRIATELY)	
☐ Client Registry	Health ☐ Facility Registry
☐ Health Worker Registry	Community ☐ Health Unit Registry
☐ National Shared Health Records	Electronics ☐ Claims Management Service
☐ National Logistics Information Management System	
☐ Telemedicine Registry	National ☐ Health Data Dictionary
REQUISITE DOCUMENTS (Attach the following documents)	
• Certificate of Incorporation (Where applicable)	
• Tax Compliance Certificate (Where applicable)	
• For Public Health Facilities – Gazette Notice	
• Certificate of Registration with the ODPC	
• Certificate of Compliance for DHS	
• Data Protection Impact Assessment Report	
• Proof of Payment	
DECLARATION	
I hereby attest that the information provided, including the attached documents, is true and accurate to the best of my knowledge. I authorize the DHA for validation and verification for legitimate purposes.	
Signature:	Date:

FORM 2 ((r. 13(2)(b))

REPUBLIC OF KENYA
DIGITAL HEALTH ACT, NO. 15 OF 2023
THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS,
2024

SELF-REGISTRATION IN THE CLIENT REGISTRY	
APPLICANT DETAILS	
• FIRST NAME:	
• MIDDLE NAME:	
• FAMILY NAME:	
• SEX:	
• DATE OF BIRTH:	
• NATIONALITY	
☐ KENYAN	☐ NON-KENYAN
IF KENYAN, PROVIDE;	
• NATIONAL IDENTITY CARD NUMBER; • VALID PASSPORT NUMBER; OR • MAISHA NUMBER; • BIRTH CERTIFICATE NUMBER (for <18yrs).	
FOR NON-KENYANS PROVIDE WHERE APPLICABLE;	
• ASYLUM-SEEKER PASS; • A MOVEMENT PASS; • A LETTER OF RECOGNITION; • A REFUGEE IDENTIFICATION CARD; OR • A CONVENTIONAL TRAVEL DOCUMENT.	
• EMAIL ADDRESS:	
• COUNTY OF RESIDENCE:	
• TEL NO.	
*UPLOAD SOFT COPY OF IDENTIFICATION DOCUMENT	
DECLARATION	
I hereby attest that the information provided and uploaded documents is true and accurate to the best of my knowledge. I authorize the DHA to validate and verify for legitimate purposes.	
Signature:	
Date:	

FORM 3 ((r. 16(5)))

**REPUBLIC OF KENYA
DIGITAL HEALTH ACT, NO. 15 OF 2023
THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS,
2024**

APPLICATION FOR REGISTRATION IN THE HEALTH WORKER REGISTRY	
APPLICANT'S DETAILS	
• FULL NAME: • ID/PASSPORT NO. • SEX: • EMAIL ADDRESS: • TEL NO.	
REGULATORY DETAILS	
• REGULATORY BODY: • REGISTRATION NUMBER: • STATUS OF PRACTICE LICENSE	
REQUISITE DOCUMENTS (Attach the following documents)	
• Valid license of practice:	
DECLARATION	
I hereby attest that the information provided, including the attached documents, is true and accurate to the best of my knowledge. I authorize the DHA to validate and verify for legitimate purposes.	
Signature:	Date:
.....	

FORM 4 ((r. 19(4)))

**REPUBLIC OF KENYA
DIGITAL HEALTH ACT, NO. 15 OF 2023
THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS,
2024**

APPLICATION FOR REGISTRATION IN THE NATIONAL LOGISTICS MANAGEMENT INFORMATION SYSTEM PLATFORM	
COMPANY DETAILS	
•	COMPANY/LTR NAME:
•	COMPANY/LTR ACCOUNT TYPE:
☐	PHARMACEUTICALS
☐	BLOOD & BLOOD PRODUCTS
☐	MEDICAL DEVICES
☐	NON-PHARMACEUTICALS
•	CERTIFICATE OF BUSINESS/REGISTRATION NO.:
•	OWNERSHIP TYPE:
☐	SOLE PROPRIETOR
☐	PRIVATE (LIMITED)
☐	PARTNERSHIP
☐	PUBLIC
•	BUSINESS TYPE:
☐	RETAIL
☐	MANUFACTURER
☐	WHOLESALE
☐	HOSPITAL
•	COMPANY PHONE NO:
•	COMPANY EMAIL ADDRESS:
•	PHYSICAL ADDRESS
APPLICANT'S DETAILS	

•	TITLE:	
•	FULL NAME:	
•	ID/PASSPORT NO.	
•	SEX:	
•	POSITION IN THE ORGANIZATION	
•	EMAIL ADDRESS:	
•	TEL NO.	
•	CITIZENSHIP	
☐	KENYAN	RESIDENT
		FOREIGN NATIONAL
REQUISITE DOCUMENTS (Attach the following documents)		
•	INCORPORATION	CERTIFICATE OF
•	POISONS BOARD LICENSE	PHARMACY &
•	COMPLIANCE CERTIFICATE	TAX
•	FEE PAYMENT RECEIPT	APPLICATION
DECLARATION		
I hereby attest that the information provided, including the attached documents, is true and accurate to the best of my knowledge. I authorize the DHA to validate and verify for legitimate purposes.		
Signature:		
Date:		

SECOND SCHEDULE

((r. 7(1)(g), (r.19(4),(r.19(7),r.22(3)(d))

REPUBLIC OF KENYA
DIGITAL HEALTH ACT, NO. 15 OF 2023
THE DIGITAL HEALTH (DATA EXCHANGE) REGULATIONS,
2024

FEES

	Component	Sub-component	Fees
1	Use of the Enterprise Service Bus	A. Health Service Delivery	(a) Onboarding to the Enterprise Service Bus (i) Level 2 and Level 3 – KES. 2,000 (ii) Level 4 – KES. 20,000 (iii) Level 5 – KES. 50,000 (iv) Level 6 – KES. 100,000 (b) Annual licence (i) Level 2 and Level 3 – KES. 1,000 (ii) Level 4 – KES. 10,000 (iii) Level 5 – KES. 15,000 (iv) Level 6 – KES. 25,000
		Telemedicine platform	(a) Onboarding into the telemedicine platform—KES. 100,000 (b) Annual licence – KES. 50,000
		B. National Logistics Management Information Services Platform	(a) Onboarding into the platform-KES. 500,000 (b) Annual retention in the platform-2% of the annual gross turnover accrued through the platform
		C. Health Insurance Providers	(a) Onboarding into the Enterprise Service Bus—KES. 500,000 (b) Annual Licence- KES 25, calculated per life per annum
2	Services offered to clients through the Enterprise Service Bus		(a) Fee for services shall be charged based on the following bands— (i) Health facility bill (KES. 1 – 9,999) – KES. 10 (ii) Health Facility bill (KES. 10,000 – 19,999) – KES . 100 (iii) Health facility bill (KES. 20,000 –

			99,999) – KES. 500 (iv)Health facility bill(KES. 100,000 and above) – KES. 2,000
--	--	--	--

Made on the, 2024.

DR. DEBORAH M. BARASA,
Cabinet Secretary for Health.